

Exhibit 205

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF NEW JERSEY
3 CAMDEN VICINAGE

- - -

4 IN RE: VALSARTAN, : MDL NO. 2875
5 LOSARTAN, AND :
6 IRBESARTAN PRODUCTS : CIVIL NO.
7 LIABILITY LITIGATION : 19-2875
8 : (RBK/JS)

9 :
10 THIS DOCUMENT APPLIES : HON. ROBERT
11 TO ALL CASES : B. KUGLER

12 - CONFIDENTIAL INFORMATION -
13 SUBJECT TO PROTECTIVE ORDER

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24 :

February 22, 2022

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25 Videotaped remote deposition of
26 KARLA V. BALLMAN, Ph.D., taken pursuant
27 to notice, was held via Zoom
28 Videoconference, beginning at 9:10 a.m.,
29 EST, on the above date, before Michelle
30 L. Gray, a Registered Professional
31 Reporter, Certified Shorthand Reporter,
32 Certified Realtime Reporter, and Notary
33 Public.

- - -

34 GOLKOW LITIGATION SERVICES
35 877.370.3377 ph| 917.591.5672
36 deps@golkow.com

<p style="text-align: right;">Page 2</p> <p>1 ZOOM APPEARANCES:</p> <p>2 LEVIN PAPANTONIO RAFFERTY PROCTOR</p> <p>3 BUCHANAN, O'BRIEN, BARR, MOUGEY, PA</p> <p>4 BY: DANIEL NIGH, ESQ.</p> <p>5 316 South Baylen Street, Suite 600</p> <p>6 Pensacola, Florida 32502</p> <p>7 (888) 435-7001</p> <p>8 dnigh@levinlaw.com</p> <p>9 Representing the Plaintiffs</p> <p>10 MAZIE SLATER KATZ & FREEMAN, LLC</p> <p>11 BY: ADAM SLATER, ESQ.</p> <p>12 103 Eisenhower Parkway, 2nd Floor</p> <p>13 Roseland, New Jersey 07068</p> <p>14 (973) 228-9898</p> <p>15 aslater@mazieslater.com</p> <p>16 Representing the Plaintiffs</p> <p>17 HOLLIS LAW FIRM, PA</p> <p>18 BY: BRETT VAUGHN, ESQ.</p> <p>19 8101 College Boulevard, Suite 260</p> <p>20 Overland Park, Kansas 66210</p> <p>21 (913) 385-5400</p> <p>22 brett@hollislawfirm.com</p> <p>23 Representing the Plaintiffs</p> <p>24 KANNER & WHITELEY, LLC</p> <p>BY: LAYNE HILTON, ESQ.</p> <p>701 Camp Street</p> <p>New Orleans, Louisiana 70130</p> <p>(504) 524-5777</p> <p>lhilton@kanner-law.com</p> <p>Representing the Plaintiffs</p> <p>MIGLIACCIO & RATHOD, LLC</p> <p>BY: MARK PATRONELLA, ESQ.</p> <p>412 H Street NE Suite 302</p> <p>Washington, DC 20002</p> <p>(202) 470-3520</p> <p>Representing the Plaintiffs</p>	<p style="text-align: right;">Page 4</p> <p>1 ZOOM APPEARANCES: (Cont'd.)</p> <p>2 GREENBERG TRAURIG, LLP</p> <p>3 BY: STEVEN M. HARKINS, ESQ.</p> <p>4 Terminus, 200</p> <p>5 3333 Piedmont Road NE, Suite 2500</p> <p>6 Atlanta, Georgia 30305</p> <p>7 (678) 553-2312</p> <p>8 harkinss@gtlaw.com</p> <p>9 - and -</p> <p>10 WALSH PIZZO O'REILLY FALANGA</p> <p>11 BY: CHRISTINE I. GANNON, ESQ.</p> <p>12 Three Gateway Center</p> <p>13 100 Mulberry Street, 15th Floor</p> <p>14 Newark, New Jersey 07102</p> <p>15 (973) 737-1017</p> <p>16 cgannon@walsh.law</p> <p>17 Representing the Defendants, Teva</p> <p>18 Pharmaceutical Industries, Ltd., Teva</p> <p>19 Pharmaceuticals USA, Inc., Actavis LLC,</p> <p>20 and Actavis Pharma, Inc.</p> <p>21 FALKENBERG IVES, LLP</p> <p>22 BY: MEGAN A. ZMICK, ESQ.</p> <p>23 230 W. Monroe Street, Suite 2220</p> <p>24 Chicago, Illinois 60606</p> <p>(312) 566-4808</p> <p>Maz@falkenbergives.com</p> <p>Representing the Defendant, Humana</p> <p>HILL WALLACK, LLP</p> <p>BY: WILLIAM P. MURTHA, JR., ESQ.</p> <p>21 Roszel Road</p> <p>Princeton, New Jersey 08543</p> <p>(609) 452-1888</p> <p>Wmurtha@hillwallack.com</p> <p>Representing the Defendant, Hetero, USA,</p> <p>Inc., Hetero Labs</p>
<p style="text-align: right;">Page 3</p> <p>1 ZOOM APPEARANCES: (Cont'd.)</p> <p>2 PIETRAGALLO GORDON ALFANO BOSICK &</p> <p>3 RASPANTI, LLP</p> <p>4 BY: FRANK H. STOY, ESQ.</p> <p>5 One Oxford Centre</p> <p>6 38th Floor</p> <p>7 Pittsburgh, Pennsylvania 15219</p> <p>8 (412) 263-1840</p> <p>9 fhs@pietragallo.com</p> <p>10 Representing the Defendant, Mylan N.V.,</p> <p>11 Mylan Pharmaceuticals Inc., and Mylan</p> <p>12 Laboratories Limited</p> <p>13 BARNES & THORNBURG, LLP</p> <p>14 BY: KARA KAPKE, ESQ.</p> <p>15 11 S. Meridian Street</p> <p>16 Indianapolis, Indiana 46204</p> <p>17 (317) 231-6491</p> <p>18 kara.kapke@btlaw.com</p> <p>19 Representing CVS Pharmacy, Inc., and Rite</p> <p>20 Aid Corporation</p> <p>21 HINSHAW & CULBERTSON, LLP</p> <p>22 BY: GEOFFREY M. COAN, ESQ.</p> <p>23 53 State Street, 27th Floor</p> <p>24 Boston, Massachusetts 02109</p> <p>(617) 213-7047</p> <p>Gcoan@hinshawlaw.com</p> <p>Representing the Defendant, ScieGen</p> <p>Pharmaceuticals, Inc.</p> <p>BUCHANAN INGERSOLL ROONEY</p> <p>BY: CHRISTOPHER B. HENRY, ESQ.</p> <p>Carillon Tower</p> <p>227 West Trade Street, Suite 600</p> <p>Charlotte, North Carolina 28202</p> <p>(704) 444-3475</p> <p>Christopher.henry@bipc.com</p> <p>Representing the Defendant, Albertson's</p> <p>LLC</p>	<p style="text-align: right;">Page 5</p> <p>1 ZOOM APPEARANCES: (Cont'd.)</p> <p>2 ALSO PRESENT:</p> <p>3</p> <p>4 VIDEOTAPE TECHNICIAN:</p> <p>5 Bill Geigert</p> <p>6 LITIGATION TECHNICIAN:</p> <p>7 Jeff Martin</p> <p>8 Lauren Massey - Paralegal</p> <p>9 (Levin Papantonio</p> <p>10 Jacqueline Suggs - Paralegal</p> <p>11 (Ulmer Berne)</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>

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I N D E X
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5 Testimony of:
6 KARLA V. BALLMAN, Ph.D.

7 By Mr. Nigh 10

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E X H I B I T S

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NO.	DESCRIPTION	PAGE
15	Ballman-1 Notice of Videotaped Oral Deposition	15
16		
17	Ballman-2 Defendants' Responses And Objections to Plaintiffs' Notice of Videotaped Deposition Of Karla V. Ballman, Ph.D.	17
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19		
20	Ballman-3 Invoices, 1/28/22 Karla Ballman Ph.D.	27
21	Ballman-4 Expert Report of Karla V. Ballman, Ph.D. 1/12/22	30
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E X H I B I T S (Cont'd.)
- - -

NO.	DESCRIPTION	PAGE
Ballman-5	Excel Spreadsheet	118
Ballman-6	Expert Report	154
	Of Dr. Madigan	
	7/7/21	

<p style="text-align: right;">Page 10</p> <p>1 reporting, please pause briefly 2 before speaking, to ensure all 3 parties are heard completely. 4 All counsel will be noted on 5 the stenographic record. 6 The court reporter is 7 Michelle Gray, and she will now 8 swear in the witness. 9 - - - 10 ... KARLA V. BALLMAN, Ph.D., 11 having been first duly sworn, was 12 examined and testified as follows: 13 - - - 14 EXAMINATION 15 - - - 16 BY MR. NIGH: 17 Q. Good morning, Doctor. Can 18 you please state and spell your last 19 name? 20 A. Good morning. My name is 21 Karla Ballman. Last name is 22 B-A-L-L-M-A-N. 23 Q. Good morning. My name is 24 Daniel Nigh, and I represent the</p>	<p style="text-align: right;">Page 12</p> <p>1 reviewed the expert reports of 2 Drs. Panigrahy and Madigan, as well as my 3 own expert report, and then I met with 4 defense counsel. 5 Q. Okay. And how many -- 6 when -- how many times did you meet with 7 defense counsel in preparation for your 8 deposition? 9 A. I think once or twice via 10 phone, and in person one -- yesterday. 11 Q. And which attorneys did you 12 meet with? 13 A. With Dr. Frank Stoy and -- 14 I'm terrible at names. So perhaps he can 15 help me out. Jason -- Mr. Jason -- 16 Q. Reefer? 17 A. Yes. 18 Q. Okay. Now, I will tell you 19 that during the deposition, just one of 20 the ground rules is obviously your 21 attorney can't help you answer questions 22 during the deposition. 23 So he did a very good job. 24 As you were staring him down, he didn't</p>
<p style="text-align: right;">Page 11</p> <p>1 plaintiffs in the valsartan MDL 2 litigation. 3 Where are you currently 4 located? 5 A. We currently are in the 6 offices of Duane Morris in New York City. 7 Q. Okay. And do you have 8 anybody else in the room with you? 9 A. Yes, I do. I have counsel 10 for the defense, Mr. Frank Stoy. 11 Q. Okay. Anyone else? 12 A. No. 13 Q. Other than laptops, do you 14 have any other electronics in the room 15 with you? 16 A. I have a calculator. 17 Q. Okay. And other than the 18 calculator and laptops, any other 19 electronics? 20 A. I do not. 21 Q. Okay. Could you please tell 22 me what you did to prepare for your 23 deposition today? 24 A. To prepare for today, I</p>	<p style="text-align: right;">Page 13</p> <p>1 give you any indication on the answer. 2 That was good. 3 A couple other ground rules 4 is, this is not an endurance test. If 5 you feel like you need a break at any 6 time, just let me know. And then also if 7 you don't understand one of my questions, 8 you know, just let me know. 9 If you answer the question, 10 I'm going to assume that you understood 11 the question. Is that fair? 12 A. Yes. 13 Q. Okay. And you said you met 14 with Frank Stoy and Jason Reefer. 15 Are there any other 16 attorneys that you met with or spoke with 17 over the phone? 18 A. There have been others on 19 the phone. But I cannot recall their 20 names at this time. 21 Q. Okay. What documents do you 22 have with you in the room today? 23 A. I have a clean copy of my 24 expert report, and that is the only</p>

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1 document that I have with me.
2 Q. And you said clean copy. I
3 think that means that there's no
4 highlights, tabs, or handwriting on that
5 document, correct?
6 A. That is correct.
7 Q. And Dr. Ballman, just a
8 couple quick questions about your
9 qualifications. You're not a
10 toxicologist, correct?
11 A. Correct.
12 Q. And before you started
13 looking at this litigation, you've never
14 published on nitrosamines previously,
15 correct?
16 A. As much as I'm aware, I have
17 not.
18 Q. And you don't ever recall
19 giving any lectures, presentations,
20 things of that nature in regards to
21 nitrosamines before you started looking
22 at this in this litigation, correct?
23 A. That is correct.
24 MR. NIGH: Okay. Let's pull

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1 up LP 1769. This is the
2 deposition notice. We'll mark
3 this as Exhibit 1.
4 (Document marked for
5 identification as Exhibit
6 Ballman-1.)
7 BY MR. NIGH:
8 Q. And I want to make sure that
9 you're able to see that document, both as
10 it comes up on the screen live, plus I
11 believe that you should also be receiving
12 a document to where if you want to, you
13 know, navigate through the pages
14 independently, you can do that as well.
15 So I believe that -- let's
16 see if I have this right. It looks like
17 you're looking at a laptop that we can
18 see on the screen. Is that where you can
19 navigate through the document, as you
20 want to navigate it?
21 A. You know, I think in theory.
22 Right now, it just says there's no files
23 in here. Do I need to download?
24 MR. STOY: If you hit

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1 refresh, it should show up and
2 you'll be able to download it.
3 THE WITNESS: Okay. Thank
4 you.
5 Yes, I have it on the laptop
6 as well as seeing it on the
7 screen.
8 BY MR. NIGH:
9 Q. Okay. And the one that
10 you're seeing on the screen is -- you
11 know, I'll direct the trial tech to move
12 through it to kind of orient you on where
13 I'm asking you questions in the document.
14 So first, if we can
15 highlight the notice to take videotaped
16 oral deposition.
17 Doctor, do you see this?
18 This is a notice for deposition?
19 A. Yes, I see that.
20 Q. And you can see your name,
21 the third line where it says, of
22 Dr. Karla Ballman, on February 22nd, '22.
23 Do you see that?
24 A. Yes.

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1 Q. Now, before today, have you
2 seen this deposition notice?
3 A. I believe I have.
4 Q. Okay. Let's take a look at
5 the third page. It's titled Exhibit A
6 and document requests.
7 Do you see this here?
8 A. I do.
9 Q. And it asks for a list of
10 documents. Do you believe that you
11 provided all responsive documents to us?
12 A. Yes, I believe I have.
13 MR. NIGH: Okay. Let's
14 take -- let's pull that down.
15 Let's take a look at LP 1797.
16 (Document marked for
17 identification as Exhibit
18 Ballman-2.)
19 BY MR. NIGH:
20 Q. I'll represent to you this
21 is the defendant's responses and
22 objections to your notice. It will
23 probably take a few seconds after I call
24 it up to land in your folder.

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1 TRIAL TECH: You may need to
2 refresh.
3 THE WITNESS: Okay.
4 BY MR. NIGH:
5 Q. Okay. And this is -- do you
6 see where it's titled "Defendant's
7 Responses and Objections to Plaintiffs'
8 Notice of Videotaped Deposition of Karla
9 Ballman"?
10 A. Yes.
11 Q. Okay. And let's turn to
12 Page 2. Sorry, Page 3, Request 2.
13 Now, Request 2 ask for any
14 notes, written or electronic, reflecting
15 consulting or litigation work that has
16 not been documented in invoices.
17 Doctor, as you were
18 reviewing -- as you were reviewing
19 studies or other documents or the master
20 complaint, did you take notes anywhere in
21 terms of, you know, jotting down your
22 thoughts in regards to those studies or
23 the complaint or the response that you
24 reviewed?

Page 19

1 MR. STOY: Object to the
2 form.
3 THE WITNESS: I only took
4 notes that were part of my
5 ultimate report. So I put notes
6 in the report.
7 BY MR. NIGH:
8 Q. Okay. Let's take a look at
9 Page 4. At the bottom you can see it
10 says, copy -- well, let me ask you
11 something.
12 When you would review the
13 scientific studies, would you make
14 highlights or underline certain things in
15 the studies themselves?
16 A. No, I did not.
17 Q. Okay. Number 4 -- Page 4,
18 Number 5 says, "Copies of any documents
19 or articles relied upon for the opinions
20 set forth in the report served, if not
21 listed."
22 And we will see that
23 Appendix B attached to your report, you
24 have a list of materials relied upon.

Page 20

1 I believe that you've
2 produced us all of those documents,
3 correct?
4 A. Yes. That was my
5 understanding.
6 Q. And now Number 6 says,
7 "Copies of any documents or articles
8 reviewed in connection with reports
9 served, whether or not listed in the
10 report or attachments thereto."
11 We don't have any additional
12 documents that were produced to us. So
13 were there no additional documents that
14 you considered as you were undertaking
15 your expert opinion in this work?
16 A. So can I ask for
17 clarification?
18 Q. Yes.
19 A. May I ask -- so if I
20 reviewed some of the articles that were
21 in the expert reports, were those not
22 supplied?
23 Q. I don't have any additional
24 articles that were supplied. So which

Page 21

1 articles do you believe that you reviewed
2 that were part of the expert reports?
3 A. Well, I thought they were
4 given under things considered. But...
5 Q. Are there additional
6 documents that you're thinking that you
7 reviewed?
8 A. Not that I relied on --
9 well, yes. It was my understanding that
10 there's also a list of materials
11 considered that concluded all the things
12 cited in the expert reports, because I
13 did look at those studies.
14 Q. Well, which of those studies
15 did you look at?
16 A. Off of the top of my head,
17 I -- I couldn't list them all with
18 complete accuracy.
19 Q. I appreciate that because,
20 you know, Dr. Panigrahy's report has
21 almost 600 cites in it, as you'll
22 probably recall.
23 A. It was more Dr. Madigan's
24 report, not Dr. Panigrahy's.

<p>Page 22</p> <p>1 Q. So you don't recall 2 reviewing any additional cited documents 3 from Dr. Panigrahy's report, correct? 4 A. Correct, not other than 5 what's listed in my Exhibit B and what 6 were in Dr. Madigan's report. 7 Q. I see. 8 MR. NIGH: Okay. We can go 9 ahead and take this down. 10 Actually, let's go ahead and 11 put that back up. We're going to 12 go back to LP 1797. 13 BY MR. NIGH: 14 Q. Doctor, I'm going to turn to 15 Page 6. Just ask you about some of your 16 prior testimony. 17 You'll see it at the top of 18 Page 6. It says, "By way of further 19 response, Dr. Ballman has testified to 20 the following matters in the past four 21 years." And it gives three bullet 22 points. 23 Do you see that? 24 A. I do.</p>	<p>Page 24</p> <p>1 mean a trial? 2 A. I mean a trial. 3 Q. And did you also testify at 4 trial in the U.S. case? 5 A. I did. 6 Q. Okay. And then you gave a 7 deposition a total of one time in that 8 case as well, correct? 9 A. That's correct. 10 Q. Okay. And for the Johnson & 11 Johnson, did you give deposition in the 12 talc case? 13 A. I did. 14 Q. Okay. Did you ever provide 15 any live testimony in any hearing or 16 trial? 17 A. I did not, no. 18 Q. For Viagra and Cialis, did 19 you provide a deposition in that case? 20 A. Yes. 21 Q. And did you ever give any 22 live testimony, either in a hearing or a 23 trial? 24 A. No.</p>
<p>Page 23</p> <p>1 Q. Okay. So you've testified 2 in Viagra and Cialis case, the talc 3 powder case, and BTG International 4 Limited cases? 5 A. Yes. 6 Q. And in each of those, did 7 you provide deposition testimony? 8 A. Yes. I testified twice in 9 the patent case, which is the third 10 bullet, I believe. And for the Canadian 11 courts, I was not deposed. So I was 12 deposed a total of three times. 13 Q. I'm sorry. When you said 14 the Canadian courts, what do you mean by 15 that? 16 A. So there was -- the case was 17 held in the U.S. courts, and then there 18 was an analogous case in the Canadian 19 courts. 20 Q. I see. So you testified in 21 the Canadian courts -- the Canadian case? 22 A. I did. 23 Q. Okay. When you said 24 testified in the Canadian case, do you</p>	<p>Page 25</p> <p>1 Q. No? Okay. 2 A. Sorry, I didn't mean to 3 interrupt you. 4 Q. Every now and then, I have a 5 little bit of a longer pause, so it's 6 okay. 7 Other than these three 8 cases, have you provided testimony in any 9 other cases in the last four years? 10 A. No. 11 Q. Okay. Now, other than the 12 last four years, have you given any 13 depositions or trial testimony in any 14 other cases before the last four years? 15 MR. STOY: Object -- 16 THE WITNESS: No. 17 MR. STOY: -- to the form. 18 Go ahead. 19 THE WITNESS: No. 20 BY MR. NIGH: 21 Q. Were you ever an expert in 22 any case other than these three cases? 23 MR. STOY: Object to the 24 form.</p>

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1 And Dr. Ballman, let me just
2 caution you with respect to your
3 response and ask you to limit it
4 to a disclosed testifying expert
5 and to not disclose any matters
6 where you may be consulting but
7 are not disclosed to testify.
8 THE WITNESS: These are the
9 only three matters in which I have
10 been a disclosed expert witness.
11 BY MR. NIGH:
12 Q. Okay. For the Viagra/Cialis
13 case, were you retained on behalf of the
14 defendants?
15 A. Yes.
16 Q. For the Johnson & Johnson
17 talc case, were you retained on behalf of
18 the defendants?
19 A. Yes.
20 Q. And for the BTG
21 International Limited case, who retained
22 you?
23 A. The manufacturers of
24 abiraterone, and I cannot remember off

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1 the top of my head. It might have been
2 Janssen Oncology.
3 Q. Okay. So in all of these
4 cases you have been retained and provided
5 testimony on behalf of pharmaceutical
6 companies; is that correct?
7 A. Yes. Yes.
8 Q. And are there any other
9 litigations where you've been retained on
10 behalf of pharmaceutical companies? I'm
11 not asking you for which litigations, but
12 are there any others in which you've been
13 retained?
14 A. No.
15 Q. Other than those three
16 litigations and this valsartan
17 litigation, have you provided an expert
18 report in any other litigation?
19 A. No.
20 MR. NIGH: Okay. We can go
21 ahead and take this down. Let
22 take a look at LP 1796.
23 (Document marked for
24 identification as Exhibit

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1 Ballman-3.)
2 MR. NIGH: We'll mark this
3 as Exhibit 3.
4 BY MR. NIGH:
5 Q. And Doctor, is this your
6 invoice for work that you billed on
7 behalf of the valsartan litigation?
8 A. Yes.
9 Q. Okay. And did you initially
10 meet with the legal team on November 29,
11 2021?
12 A. For this particular expert
13 report, yes.
14 Q. When did you first meet with
15 any of the lawyers for the valsartan
16 litigation?
17 A. Off of the top of my head, I
18 do not remember an exact date. But I
19 think I was contacted maybe late 2020 or
20 early 2021 and retained at that point in
21 terms of signing a letter of agreement.
22 Q. Did you do any work from the
23 date that you signed that retainer
24 agreement until November 29th, 2021?

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1 A. I did not.
2 Q. Okay. So no other work on
3 valsartan in any capacity before
4 November 29th, 2021?
5 A. That's correct.
6 Q. Okay. And if you turn the
7 page, we can see that you spent a total
8 of 41 and a half hours; is that correct?
9 A. Yes.
10 Q. And your total charge as of
11 January 12th, 2021, would be \$16,600?
12 A. Yes.
13 Q. Now, how many hours have you
14 spent on valsartan after January 12,
15 2021, approximately?
16 A. I'd say approximately
17 between 15 to 20 hours.
18 Q. And that would be -- part of
19 that time would be preparing for the
20 deposition?
21 A. That is correct.
22 MR. NIGH: Okay. Let's go
23 ahead and take that down.
24 Let's mark your expert

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1 report as Exhibit 4.
2 (Document marked for
3 identification as Exhibit
4 Ballman-4.)
5 MR. NIGH: That's LP 1768.
6 BY MR. NIGH:
7 Q. Doctor, when you were
8 initially contacted -- strike that.
9 Start over.
10 Doctor, when you were asked
11 to do -- to write an expert report, what
12 was the task that you were asked to do?
13 A. So I was asked to determine
14 whether there is evidence that supports
15 the use of proposed thresholds that were
16 based upon the expert reports of
17 Drs. Panigrahy and Madigan, and then also
18 to try to try to determine how the
19 thresholds were derived.
20 Q. And did you have difficulty
21 determining how the thresholds were
22 derived?
23 MR. STOY: Object to the
24 form of the question.

Page 31

1 You can answer.
2 THE WITNESS: I am not sure
3 what you mean by difficulty.
4 I mean, I tried various
5 different things to try to
6 determine how the thresholds were
7 derived. But there was no
8 explanation as to how the
9 thresholds were derived.
10 So that's why I had to try
11 many different ways of trying to
12 come up with those thresholds.
13 BY MR. NIGH:
14 Q. Now, when you said the
15 thresholds, do you mean the LCEs
16 calculated by Madigan and Panigrahy, or
17 do you mean the thresholds as described
18 in the medical monitoring complaint?
19 A. I mean the thresholds as
20 described in the medical monitoring
21 complaint.
22 Q. When you looked at the LCEs
23 as calculated by Dr. Madigan, did you
24 understand how he was calculating those

Page 32

1 LCEs?
2 A. Yes. I was able to
3 reproduce the numbers that he calculated
4 and, yes.
5 Q. And you didn't -- your
6 report doesn't list any criticisms of how
7 he calculated those LCEs, correct?
8 A. I did not find any problems
9 with the math that he did, no.
10 Q. Okay. And were you able to
11 see how Dr. Panigrahy calculated the
12 LCEs?
13 A. Again, given his explanation
14 of the formula he used and the values
15 that he used in the formulas, I too was
16 able to match the numbers that he
17 ultimately produced.
18 Q. Now, both Panigrahy and
19 Madigan had some different approaches as
20 to how they calculated LCE -- their LCEs,
21 correct?
22 MR. STOY: Object to the
23 form.
24 You can answer.

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1 THE WITNESS: I'm not sure
2 if their approach is different. I
3 think they used different values.
4 BY MR. NIGH:
5 Q. Okay. So for example, in
6 calculating LCEs for Hidajat, Dr. Madigan
7 didn't give any adjustment for the amount
8 that would actually be inhaled versus
9 exhaled, correct?
10 A. That is correct. He did not
11 make an adjustment for the amount that
12 might be exhaled.
13 Q. And Dr. Panigrahy did make
14 an adjustment for that, correct?
15 A. Yes, he did make an
16 adjustment for that.
17 Q. And the ages that they used
18 in terms of the amount of years that they
19 would be ingesting NDMA, the ages they
20 used were different between the two,
21 correct?
22 A. I -- so I'm not able to
23 answer that without looking at their
24 reports. I know they both used some

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<p>1 ages, and they described how they used 2 those ages. So this may be one of those 3 values that I mentioned differed between 4 the two experts. 5 Q. Have you ever calculated 6 lifetime cumulative exposures in your 7 work? 8 A. My work has never called for 9 a calculation of lifetime cumulative 10 exposures because that number in the 11 research I do in cancer research is not 12 really a meaningful number. So no. 13 Q. Now, have you ever reviewed 14 toxicologists' opinions where they 15 calculate LCEs, or lifetime cumulative 16 exposures? 17 A. I have not. 18 Q. So this would be the first 19 time that you're looking at lifetime 20 cumulative exposures? 21 MR. STOY: Object to the 22 form of the question. 23 THE WITNESS: It is the 24 first time that I was doing a</p>	<p>1 undertook your task of looking at LCEs, 2 did you ever look at anything in terms of 3 how much NDMA infants, children, and 4 adolescents are being exposed to compared 5 to adults? 6 MR. STOY: Object to the 7 form. Scope. 8 THE WITNESS: Again, that is 9 outside the scope of what I was 10 asked to do. 11 I was asked to review the 12 lifetime cumulative thresholds 13 that were in the medical 14 monitoring plan and then determine 15 whether or not there is evidence 16 to support the use of those 17 thresholds, and then to determine 18 how those thresholds might have 19 been derived given the information 20 in the two expert reports of 21 Dr. Panigrahy and Madigan. 22 BY MR. NIGH: 23 Q. So you wouldn't have any 24 understanding that the lifetime</p>
Page 35	Page 37
<p>1 calculation of lifetime cumulative 2 exposures. I am not sure if it's 3 the first time I've ever seen the 4 concept or read a paper with them. 5 BY MR. NIGH: 6 Q. Are you aware that, in 7 calculating lifetime cumulative 8 exposures, it's common -- lifetime 9 cumulative exposures in diet that it's 10 common not to include the adolescent 11 years or childhood years in calculating 12 LCEs? 13 MR. STOY: Object to the 14 form. 15 THE WITNESS: That is 16 outside the scope of my charge. 17 But to my knowledge, I do not know 18 whether or not the childhood years 19 are included or not within those 20 exposures. I would think it would 21 depend upon what the individual is 22 being exposed to. 23 BY MR. NIGH: 24 Q. Do you have -- when you</p>	<p>1 cumulative exposures that Madigan and 2 Panigrahy calculated are conservative 3 because they include the years for their 4 adolescent years and childhood years, 5 correct? You have no opinion on that? 6 MR. STOY: Object to the 7 form. 8 THE WITNESS: Again, that 9 was outside my scope. I just took 10 the numbers, because it was 11 referenced in the medical 12 monitoring report that it was 13 based upon the information in 14 those two expert reports. 15 Within those two expert 16 reports, I do not recall a 17 discussion as to whether or not it 18 was a conservative approach to 19 include the infant and adolescent 20 years. 21 BY MR. NIGH: 22 Q. So you would have no opinion 23 on that, correct? 24 A. Again, I -- outside the</p>

<p>Page 38</p> <p>1 scope of what I was asked to do. So at 2 this point I would have to do some 3 research as to when those should be or 4 should not be included, so I cannot 5 render an opinion right now. 6 Q. Doctor, your opinions of the 7 program are based on your review of 8 Madigan and Panigrahy's LCEs, correct? 9 A. They are based upon the 10 expert reports in which both expert 11 reports did have a component that 12 calculated LCEs. 13 Q. So in reaching your 14 opinions, it would be important for you 15 to understand Madigan and Panigrahy's 16 opinions in order to form your opinions 17 that criticize the plaintiffs' proposed 18 medical monitoring program, correct? 19 MR. STOY: Object to the 20 form. 21 THE WITNESS: I'm sorry. 22 I'm trying to digest that 23 question. I'm not sure what I'm 24 being asked.</p> <p>Page 39</p> <p>1 Nowhere in their report did 2 I see them calculate lifetime 3 cumulative thresholds or a 4 discussion of that. 5 The only place that I did 6 see that was in the medical 7 monitoring document. 8 BY MR. NIGH: 9 Q. I'm trying to understand -- 10 I'm simply asking you that in order to 11 form your opinions that criticize the 12 plaintiffs' proposed medical monitoring 13 program, it would be important for you to 14 understand Madigan and Panigrahy's 15 opinions, correct? 16 MR. STOY: Object to the 17 form. Asked and answered. 18 THE WITNESS: I'm not sure. 19 Opinions to what? 20 I think it's important to 21 understand, you know, what they 22 stated and their conclusions, 23 which I believe I do, to some 24 extent, as well as how they</p>	<p>Page 40</p> <p>1 generated their lifetime 2 cumulative exposures, which I 3 mentioned I was able to replicate. 4 BY MR. NIGH: 5 Q. On the task that you were 6 set out, when you just said that you were 7 asked to determine whether there's 8 evidence that supports the use of the 9 proposed thresholds based upon the expert 10 reports of Dr. Panigrahy and Madigan. 11 So your task was to see if 12 there's support and the basis of it is 13 the expert reports of Dr. Panigrahy and 14 Madigan, correct? 15 MR. STOY: Object to the 16 form. 17 THE WITNESS: I did use 18 those expert reports, because they 19 were cited by the medical 20 monitoring plan as the basis for 21 trying to see if there's evidence 22 to be able to propose lifetime 23 cumulative thresholds. 24 BY MR. NIGH:</p> <p>Page 41</p> <p>1 Q. So it would be important for 2 you, as you formulate your opinions, to 3 understand the opinions of Dr. Panigrahy 4 and Madigan, correct? 5 MR. STOY: Objection to 6 form. Asked and answered. 7 THE WITNESS: Again, I'm not 8 sure -- I do understand their 9 conclusion. But I don't think it 10 necessitates me to agree 11 necessarily with their 12 conclusions. 13 BY MR. NIGH: 14 Q. And if you misunderstood the 15 opinions of Dr. Panigrahy and Madigan, 16 then that could be problematic for your 17 criticisms, correct? 18 MR. STOY: Objection to 19 form. Incomplete hypothetical. 20 THE WITNESS: I do not 21 believe I misunderstood their 22 conclusions. 23 BY MR. NIGH: 24 Q. I didn't ask you if --</p>
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<p style="text-align: right;">Page 42</p> <p>1 whether or not you believe you 2 misunderstood their conclusions. 3 I asked you, if you 4 misunderstood the opinions of Dr. Madigan 5 and Panigrahy, then that could be 6 problematic for your criticisms, correct? 7 MR. STOY: Same objection. 8 THE WITNESS: I believe it 9 depends. So how might I miss -- 10 I'm not sure how I might 11 misunderstand in a way that might 12 affect what I had done. 13 I think there could be 14 different -- different types of 15 misunderstanding that might lead 16 to different things. So I'm just 17 not sure how to answer that. 18 BY MR. NIGH: 19 Q. I used the word "could" 20 intentionally in my question. And I want 21 to focus on that again. 22 I asked you if you 23 misunderstood the opinions of Dr. Madigan 24 and Panigrahy, then that could be</p>	<p style="text-align: right;">Page 44</p> <p>1 Dr. Panigrahy and Dr. Madigan, and your 2 conclusions and criticisms would still be 3 accurate? 4 A. Again, I -- I would need to 5 know what completely misunderstands 6 means. 7 As I stated, I do not 8 believe I misunderstood their 9 conclusions. As to their opinions, they 10 may have had opinions that throughout 11 that weren't in their conclusions. 12 I just -- that's just too 13 broad for me to answer. I'm sorry. 14 Q. But we can agree that 15 Dr. Panigrahy and Dr. Madigan's opinions 16 form the basis -- or form a basis of your 17 opinions, correct? 18 MR. STOY: Object to the 19 form. 20 Go ahead. 21 THE WITNESS: No, I don't 22 think that's true. I don't think 23 it's based on their opinions. 24 I think it's based on their</p>
<p style="text-align: right;">Page 43</p> <p>1 problematic for your criticisms, correct? 2 MR. STOY: Same objection. 3 THE WITNESS: Again, it's 4 very hard to answer that 5 hypothetical without understanding 6 in what manner I may have 7 misunderstood their conclusions. 8 I think that the answer 9 depends on the type of 10 misunderstanding. 11 BY MR. NIGH: 12 Q. Do you believe that you 13 could completely misunderstand their 14 opinions and your conclusions and 15 criticisms would still be accurate? 16 MR. STOY: Objection to 17 form. Incomplete hypothetical. 18 THE WITNESS: I'm sorry. 19 Can you repeat that question 20 again? I just want to make sure I 21 heard it. 22 BY MR. NIGH: 23 Q. Do you believe that you can 24 completely misunderstand the opinions by</p>	<p style="text-align: right;">Page 45</p> <p>1 complete reports and the 2 information that is in the 3 reports, that -- because the 4 medical monitoring plan just cited 5 that that was the basis. 6 It did not state that their 7 opinions was the basis for 8 deriving the stated lifetime 9 cumulative thresholds. 10 BY MR. NIGH: 11 Q. So you believe that 12 Dr. Panigrahy and Dr. Madigan's complete 13 reports and the information in those 14 reports would form part of the basis of 15 your opinions and criticisms? 16 A. Within the scope of what I 17 was asked to do, was to determine whether 18 there is evidence that supports the use 19 of the proposed thresholds based upon the 20 expert reports. So I did use those 21 expert reports to look to see if I felt 22 there was evidence to support a proposed 23 lifetime cumulative threshold. 24 Q. So in order to examine</p>

<p>Page 46</p> <p>1 whether or not there is evidence to 2 support a proposed lifetime cumulative 3 threshold, it would have been necessary 4 for you to review and understand 5 Dr. Panigrahy and Dr. Madigan's reports, 6 correct? 7 MR. STOY: Object to the 8 form. 9 THE WITNESS: Yes, it 10 would -- it would require me -- 11 and I did review their reports, 12 and I believe I did understand 13 what they were saying. 14 BY MR. NIGH: 15 Q. Now, some of the work that 16 you undertook were calculations, correct? 17 A. Correct. 18 Q. And if you are missing 19 certain steps in a calculation, then your 20 ultimate answer would be incorrect, or 21 could be incorrect, correct? 22 MR. STOY: Objection. 23 Incomplete hypothetical. 24 Go ahead.</p> <p>Page 47</p> <p>1 THE WITNESS: The 2 calculations I undertook was to 3 try to replicate the proposed 4 thresholds in the medical 5 monitoring plan. 6 And there was no information 7 really provided within those 8 plans, other than that they relied 9 upon the expert reports. 10 So I had no steps to follow. 11 BY MR. NIGH: 12 Q. Now, let's take a look at 13 Page 14 of your report. 14 MR. NIGH: And that first 15 full paragraph, if we can put that 16 up on the screen, that first full 17 paragraph. 18 BY MR. NIGH: 19 Q. It says, "In the absence of 20 clearly specified" -- 21 MR. NIGH: We can go down. 22 It's not on the screen here. 23 BY MR. NIGH: 24 Q. "In the absence of clearly</p>	<p>Page 48</p> <p>1 specified values, I tried to determine 2 the impurity amounts for NDMA and NDEA in 3 320-milligram of valsartan using the LCEs 4 in Dr. Madigan's report and the time 5 thresholds proposed for each manufacturer 6 proposed by the plaintiffs." 7 Do you see that? 8 A. Yes. 9 Q. And you believe that this 10 was part of the task that you were asked 11 to perform by defense counsel, correct? 12 A. Yes. I was asked to try to 13 determine how the proposed thresholds in 14 the medical monitoring plan were derived. 15 Q. And next you said, "I would 16 note at the outset that any statistical 17 methodology requiring a reviewer to back 18 into the data in this manner -- that is, 19 to use the outcomes to try to determine 20 the inputs -- is at best incomplete and 21 likely invalid." 22 What do you mean by that 23 sentence? 24 A. I mean that's not a</p> <p>Page 49</p> <p>1 scientifically sound method to do 2 something. What would be scientifically 3 sound is if a threshold is proposed, that 4 it's very clear what was used in order to 5 come up with the threshold so someone 6 else could replicate the work easily in 7 terms of what formula was used, in terms 8 of what inputs were used, and so forth. 9 And so what I mean is within 10 the medical monitoring report, there are 11 just thresholds proposed with a citation 12 that says, "This is based upon the expert 13 reports of Dr. Panigrahy and Dr. 14 Madigan," in whom's reports did not 15 propose a lifetime cumulative threshold. 16 And so there were many 17 assumptions missing in the derivation of 18 those thresholds. And so if there's 19 missing assumptions, one has to try to 20 make guesses, and that's not a very 21 scientific method. 22 Q. So the task that you were 23 asked to carry out would not have been a 24 very scientific method because you're</p>
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1 having to back into the data?
2 MR. STOY: Object to the
3 form. Misstates testimony.
4 THE WITNESS: No. What I
5 was saying was that the medical
6 monitoring report that proposed
7 the thresholds did not provide a
8 scientific basis for how those
9 thresholds were proposed, other
10 than saying that they relied upon
11 the expert reports of
12 Dr. Panigrahy and Dr. Madigan.
13 And within those reports,
14 there are no lifetime cumulative
15 thresholds proposed, nor is there
16 a discussion of how those might be
17 derived.
18 BY MR. NIGH:
19 Q. Yeah, but you were asked to
20 try and recreate or to do the math as to
21 how those lifetime cumulative thresholds
22 were proposed, correct?
23 A. I was asked in the sense
24 that perhaps, you know, their -- I don't

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1 believe -- I was asked as an expert to
2 review those expert reports to see if
3 there was some methodology proposed on
4 how those were derived.
5 Q. So you were a reviewer,
6 correct?
7 MR. STOY: Object to the
8 form.
9 THE WITNESS: No. I'm an
10 expert.
11 I, you know, I -- this is
12 basically a classification
13 problem.
14 It's classifying people as
15 to those at an increased risk for
16 cancer and those not at increased
17 risk for cancer. And I have done
18 several classification studies
19 within cancer.
20 And so I took the approach
21 of, you know, what I would expect
22 to see in order to have scientific
23 evidence in support of the
24 lifetime cumulative thresholds.

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1 BY MR. NIGH:
2 Q. When you attempted to
3 calculate these thresholds, did you also
4 find that it was difficult for you to do
5 so because you were having to back into
6 the data in that manner?
7 A. I found it was difficult to
8 do so, because it was essentially one
9 equation and two unknowns. And that is
10 just something that cannot be solved.
11 Q. Now, when you said one
12 equation and two unknowns, did you come
13 up with two unknowns because you couldn't
14 figure out how to reach those LCEs from
15 valsartan -- from the valsartan pills
16 in -- the NDMA and/or NDEA in the
17 valsartan pills?
18 MR. STOY: Object to the
19 form.
20 THE WITNESS: So I -- as I
21 mentioned, I was able to reproduce
22 the LCEs that are proposed or that
23 are mentioned in both the expert
24 reports, because those are clearly

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1 stated as to, you know, the length
2 of exposure, the amount of
3 impurity within the valsartan, and
4 you know, the necessary things in
5 order to come up with the lifetime
6 cumulative exposure.
7 I did do that.
8 BY MR. NIGH:
9 Q. So you didn't have any
10 criticisms of how Madigan or Panigrahy
11 calculated their LCEs, correct?
12 MR. STOY: Objection. Asked
13 and answered.
14 Go ahead.
15 THE WITNESS: I believe I
16 did answer that before. And I
17 said that, given what they said
18 they used and the equation they
19 used, I was able to match the
20 numbers that they produced.
21 BY MR. NIGH:
22 Q. I see.
23 Now, in terms of trying to
24 understand how three months of ZHP -- or

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1 products -- or valsartan pills that used
2 ZHP API, were you able to understand how
3 that could reach increased risk of
4 gastric cancer?
5 MR. STOY: Object to the
6 form.
7 THE WITNESS: So I do not
8 believe that -- there's an
9 assumption in there that I'm
10 having a hard time with, in that I
11 don't believe there's been
12 evidence that any sort of exposure
13 to any level of impurity within
14 valsartan leads to an increased
15 risk of gastric cancer.
16 So beyond that, then it's
17 hard to answer the rest of it.
18 BY MR. NIGH:
19 Q. I'm sorry. You don't
20 believe there's been evidence that any
21 sort of exposure to any level of impurity
22 within valsartan leads to an increased
23 risk of gastric cancer?
24 A. I believe that there has

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1 been associations observed in
2 observational studies of an association
3 between levels of impurities within
4 valsartan and increased gastric cancer,
5 but that's not causal. And so all I can
6 say is there have been published
7 associations.
8 Q. Did you review
9 Dr. Panigrahy's report where he gives the
10 opinion that ingestion of NDMA in
11 valsartan pills causes or is capable of
12 causing gastric cancer?
13 MR. STOY: Objection.
14 Scope.
15 THE WITNESS: Yeah, I was
16 not asked to opine upon the
17 causation question. So that is
18 outside my scope.
19 BY MR. NIGH:
20 Q. Okay. You gave the answer
21 in terms of an assumption. You don't
22 believe there's been any evidence that
23 any sort of exposure to any level of
24 impurity within valsartan leads to an

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1 increased risk of gastric cancer.
2 And you reviewed
3 Dr. Panigrahy's report, correct?
4 A. Yes.
5 Q. So Dr. Panigrahy provides
6 that evidence, or at least that opinion,
7 expert opinion, correct?
8 MR. STOY: Object to the
9 form.
10 THE WITNESS: You know, I
11 don't have Dr. Panigrahy's report
12 in front of me.
13 You know, he may have opined
14 that the trace impurities within
15 valsartan caused gastric cancer.
16 And if he did so, I do not
17 agree with that conclusion.
18 BY MR. NIGH:
19 Q. Where did you see the word
20 "trace impurities" anywhere?
21 A. I did not see it anywhere.
22 But that -- I mean, there are impurities
23 within valsartan, and that's not the bulk
24 of what's in valsartan. So that's why I

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1 called it a trace.
2 Q. Do you believe that having
3 NDMA that's over 200 times the acceptable
4 levels set by the FDA are trace?
5 MR. STOY: Objection to
6 form. Objection. Beyond the
7 scope of her report.
8 THE WITNESS: So I'm not a
9 regulator. And so -- and it's
10 beyond -- again, I didn't look at
11 sort of causation.
12 But having said that, I know
13 that the level set by the FDA is a
14 theoretical level, and it's based
15 upon a level under which they
16 believe it is safe.
17 That does not imply that
18 anything -- you know, that levels
19 above that number are unsafe. And
20 they did not set a threshold for
21 what they believe to be an unsafe
22 level.
23 They've only set a threshold
24 for what they believe to be a safe

<p>Page 58</p> <p>1 level, not necessarily based on 2 scientific evidence -- there is no 3 evidence in humans -- but based 4 upon sort of assumptions they made 5 in doing their calculation, which 6 is in their right to do as a 7 regulator. 8 BY MR. NIGH: 9 Q. Have you reviewed FDA 10 documents where they state that there 11 should be no NDMA in medications? 12 MR. STOY: Objection. 13 Beyond the scope. 14 THE WITNESS: Again, that's 15 beyond the scope of what I was 16 asked to do. So I did not review 17 those -- any FDA documents that -- 18 with that statement in it, as far 19 as I'm aware. 20 BY MR. NIGH: 21 Q. When you said they did not 22 set a threshold for what they believed to 23 be an unsafe level, why do you believe 24 that the FDA then asked all the</p> <p>Page 59</p> <p>1 medication that's over 96 nanograms of 2 NDMA to be recalled? 3 MR. STOY: Objection. Form. 4 Calls for speculation. Beyond the 5 scope. 6 THE WITNESS: Yeah, again 7 I'm not a regulator. And I don't 8 know what fed into FDA's decisions 9 to do or not to do something. 10 All I know is that the level 11 they decided to set is a level 12 that they felt that anything below 13 that would be safe. 14 BY MR. NIGH: 15 Q. Now, you said that they 16 didn't say anything about levels above it 17 being unsafe. 18 But they did ask for all 19 that medication to be recalled. So you 20 don't equate a recall with unsafe? 21 MR. STOY: Objection. Form. 22 Scope. 23 THE WITNESS: Again, I'm not 24 a regulator. All I can say is</p>	<p>Page 60</p> <p>1 that, you know, they made the 2 decision. They set the level. 3 And they set a level that under 4 which they knew it would be safe. 5 And they did not set a level 6 above which it would be unsafe. 7 And I believe that as 8 regulators, they just want to make 9 sure that, you know, there's clear 10 evidence that it is safe, but it 11 doesn't mean that anything above 12 it is unsafe. 13 BY MR. NIGH: 14 Q. What do you mean by trace? 15 You said trace levels of NDMA. What do 16 you mean by trace? What's your 17 definition? 18 A. My definition is, if it 19 makes up a very, very small amount of 20 what the bulk is of the object. 21 I know that's very 22 imprecise, and so -- and I know lawyers 23 like precise language. And so that's 24 just the way that I was using trace. No</p> <p>Page 61</p> <p>1 technical definition. 2 Q. Okay. Did you review any 3 documents that discussed how NDMA and 4 NDEA are carcinogenic at very low levels? 5 MR. STOY: Object to the 6 form. Misstates the record. 7 Beyond the scope. 8 THE WITNESS: The only 9 documents that I think discuss 10 that may have been the expert 11 reports, and it was levels within 12 animals. 13 I don't think there's been 14 any data within humans as to what 15 the impact is of low levels of 16 NDMA. 17 BY MR. NIGH: 18 Q. Did you review the WHO 2002 19 document on NDMA? 20 A. I did not. 21 Q. But you did review dietary 22 studies that discuss increased risk of 23 cancer at higher levels of NDMA 24 ingestion, correct?</p>
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<p style="text-align: right;">Page 62</p> <p>1 MR. STOY: Object to the</p> <p>2 form.</p> <p>3 THE WITNESS: I did review</p> <p>4 some dietary studies that showed</p> <p>5 an association with -- some</p> <p>6 studies showed an association with</p> <p>7 increasing levels of NDMA and</p> <p>8 increased cancer risk. They just</p> <p>9 showed an association.</p> <p>10 BY MR. NIGH:</p> <p>11 Q. And they showed an</p> <p>12 association at trace levels, correct?</p> <p>13 MR. STOY: Object to the</p> <p>14 form.</p> <p>15 THE WITNESS: Again, I don't</p> <p>16 have a technical definition of</p> <p>17 trace levels.</p> <p>18 So -- and it was in diet.</p> <p>19 I just don't know.</p> <p>20 BY MR. NIGH:</p> <p>21 Q. Now, using your definition</p> <p>22 for trace levels in valsartan, a very</p> <p>23 small amount of the product, the amount</p> <p>24 of NDMA that was in food, the nanograms</p>	<p style="text-align: right;">Page 64</p> <p>1 There is an association, but</p> <p>2 that's all I can say.</p> <p>3 BY MR. NIGH:</p> <p>4 Q. Before we start going down</p> <p>5 that rabbit tunnel, you didn't do</p> <p>6 anything to review the epidemiology in</p> <p>7 this case and make any causation</p> <p>8 opinions, correct?</p> <p>9 A. Reviewing the epidemiology</p> <p>10 as a whole in terms of coming up with a</p> <p>11 causation opinion, I did not do.</p> <p>12 That would require me to do</p> <p>13 a full literature search.</p> <p>14 All I did was looked at the</p> <p>15 studies that were cited by Dr. Panigrahy</p> <p>16 and Dr. Madigan that had to do with human</p> <p>17 studies.</p> <p>18 Q. And it's rare that an</p> <p>19 individual study will say that one thing</p> <p>20 causes another, correct?</p> <p>21 MR. STOY: Object to the</p> <p>22 form.</p> <p>23 THE WITNESS: I think it</p> <p>24 depends. You know, it depends.</p>
<p style="text-align: right;">Page 63</p> <p>1 would be a very small percentage of the</p> <p>2 food, correct? So they would be trace?</p> <p>3 MR. STOY: Objection to form</p> <p>4 and scope.</p> <p>5 THE WITNESS: Yeah, again,</p> <p>6 that -- it's outside the scope of</p> <p>7 what I was asked to do.</p> <p>8 But as I said, there was an</p> <p>9 association. And the amounts, as</p> <p>10 you stated, are probably, you</p> <p>11 know, quite small compared to the</p> <p>12 bulk of the foodstuffs that people</p> <p>13 have ingested.</p> <p>14 However, none of these</p> <p>15 studies establish causation. So</p> <p>16 the increased risk with higher</p> <p>17 levels of NDMA in these studies</p> <p>18 well could be because maybe</p> <p>19 obesity, that people that are more</p> <p>20 obese, eat more. And we know that</p> <p>21 obesity is associated with many</p> <p>22 cancers.</p> <p>23 So there's many confounding</p> <p>24 factors.</p>	<p style="text-align: right;">Page 65</p> <p>1 If you're doing it in</p> <p>2 animals, because you can do a</p> <p>3 randomized trial, you can say that</p> <p>4 yes, in this study, the animals</p> <p>5 that were randomized to agent X</p> <p>6 had a higher level of tumor</p> <p>7 formation than the animals</p> <p>8 randomized to control.</p> <p>9 So in that situation I think</p> <p>10 they would say that the agent X</p> <p>11 causes cancer in animals.</p> <p>12 BY MR. NIGH:</p> <p>13 Q. It's rare that an individual</p> <p>14 human epidemiology study will say that</p> <p>15 one thing causes another, correct?</p> <p>16 A. Again, I think it just</p> <p>17 depends upon what is being addressed.</p> <p>18 And again, if you -- I live</p> <p>19 in the world of clinical trials. And I</p> <p>20 believe that, you know, we do make</p> <p>21 conclusions based on one study as to</p> <p>22 whether or not a drug benefits a patient</p> <p>23 or not.</p> <p>24 Q. In all of your studies that</p>

<p>Page 66</p> <p>1 you've published -- how many studies have</p> <p>2 you published? Can you give an estimate?</p> <p>3 A. Oh, I don't know. Somewhere</p> <p>4 over 225.</p> <p>5 Q. In all of your studies that</p> <p>6 you published, are there any human</p> <p>7 studies where you -- where you or the</p> <p>8 study gave the opinion that one substance</p> <p>9 causes an increased -- one substance</p> <p>10 causes an adverse event?</p> <p>11 MR. STOY: Object to the</p> <p>12 form.</p> <p>13 THE WITNESS: Again, I do</p> <p>14 many clinical trials. But I have</p> <p>15 to say -- and we've actually</p> <p>16 studied this -- that adverse</p> <p>17 events are quite tricky.</p> <p>18 And so we would say that, in</p> <p>19 a clinical trial, that, you know,</p> <p>20 one arm had a higher adverse event</p> <p>21 rate than the other arm. And if</p> <p>22 it was a randomized trial and</p> <p>23 blinded -- because if it's not</p> <p>24 blinded, there are biases in there</p> <p>Page 67</p> <p>1 because physicians know what drugs</p> <p>2 the people are getting, and so</p> <p>3 they might be more inclined to</p> <p>4 call an adverse event something</p> <p>5 that they think is more toxic than</p> <p>6 something else.</p> <p>7 So, you know, we do make the</p> <p>8 observation that in the control</p> <p>9 arm, if it were placebo</p> <p>10 controlled, compared to the</p> <p>11 treatment arm, if the treatment</p> <p>12 arm has a higher adverse event</p> <p>13 rate, we would say that higher</p> <p>14 rate is due to the treatment.</p> <p>15 But again, that would have</p> <p>16 to be a double-blind</p> <p>17 placebo-controlled trial.</p> <p>18 BY MR. NIGH:</p> <p>19 Q. So for you to make that</p> <p>20 opinion in an individual study, that</p> <p>21 treatment causes an adverse event, you</p> <p>22 would want it to be a clinical trial and</p> <p>23 a double-blinded clinical trial, correct?</p> <p>24 A. That is one instance in</p>	<p>Page 68</p> <p>1 which one would be able to make such a</p> <p>2 conclusion.</p> <p>3 Q. In all of the human</p> <p>4 epidemiology studies, not the clinical</p> <p>5 trial studies, that you published -- you</p> <p>6 have published some epidemiology studies</p> <p>7 that are not clinical trials, correct?</p> <p>8 A. Correct.</p> <p>9 Q. In all of the epidemiology</p> <p>10 studies that you've published, was there</p> <p>11 ever an opinion that one agent or</p> <p>12 treatment causes an adverse event?</p> <p>13 MR. STOY: Object to the</p> <p>14 form.</p> <p>15 THE WITNESS: I'm sorry.</p> <p>16 What I'm trying to think of is --</p> <p>17 I'm trying to think if I've ever</p> <p>18 done a study where the primary</p> <p>19 endpoint was an adverse event.</p> <p>20 I found many studies that</p> <p>21 establish associations, and some</p> <p>22 of them could be an association</p> <p>23 with an adverse event.</p> <p>24 BY MR. NIGH:</p> <p>Page 69</p> <p>1 Q. Can you think of a single</p> <p>2 epidemiology study that you reviewed</p> <p>3 where there was opinion that one agent or</p> <p>4 treatment caused an adverse event, not</p> <p>5 just association, but caused?</p> <p>6 MR. STOY: Object to the</p> <p>7 form.</p> <p>8 THE WITNESS: So in my work,</p> <p>9 and why I'm pausing to some</p> <p>10 extent, is I had been an associate</p> <p>11 editor and then an deputy editor</p> <p>12 for the Journal of Clinical</p> <p>13 Oncology.</p> <p>14 In that role, over the years</p> <p>15 I probably have reviewed and</p> <p>16 evaluated thousands of studies.</p> <p>17 I cannot say with certainty</p> <p>18 that I have not seen such a study</p> <p>19 that has made that conclusion.</p> <p>20 BY MR. NIGH:</p> <p>21 Q. But you can't think of a</p> <p>22 single study that has made that</p> <p>23 conclusion, correct?</p> <p>24 A. Sitting right here, right</p>
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<p>Page 70</p> <p>1 now in front of you, I can't come up with 2 much of anything. But no, I cannot come 3 up with a -- I cannot point to study X 4 right now. 5 Q. And that's because causal 6 opinions in a single epidemiology study 7 are rarely reached, correct? 8 MR. STOY: Object to the 9 form. 10 THE WITNESS: Again, this is 11 going outside the scope of what I 12 was asked to do. 13 I was not asked to speak on 14 causation. But when one tries to 15 establish causation based on 16 observational studies -- and I'm 17 not sure if you mean that. Again, 18 clinical trials, yes, you can make 19 such a conclusion, as I've said. 20 And I don't know if those 21 fall under epidemiology studies or 22 not, in -- I don't know. 23 BY MR. NIGH: 24 Q. Let me rephrase my question.</p> <p>Page 71</p> <p>1 And that's because causal 2 opinions in a single observational study 3 are rarely reached, correct? 4 A. Again, I was not asked to 5 speak on causation. But if I did a 6 causal analyses, yes, I would not base my 7 opinion, one way or the other, on the 8 conclusion of a single study, whether the 9 study concluded X causes Y or not. 10 Q. That's not my question. 11 I'm asking you about a 12 single observational study, not you 13 looking at a single observational study, 14 okay. 15 So my question is: In a 16 single observational study, the study 17 authors rarely reach causal opinions, 18 correct? 19 MR. STOY: Object to the 20 form. 21 Objection. Asked and 22 answered. 23 THE WITNESS: Again, I don't 24 know what you mean by rarely.</p>	<p>Page 72</p> <p>1 You know, I think many 2 studies at the end, the editors 3 would not allow, if just an 4 association were established -- 5 well, if it were an observe -- 6 depends upon the study design and 7 how well it was done. 8 If it was not a very good 9 study, meaning there was lots of 10 confounding in it, then yes, one 11 would not be able to conclude at 12 the end of the study that X causes 13 Y, just due to the residual 14 confounding in the study design. 15 BY MR. NIGH: 16 Q. Can you think of a single 17 observational study where the study 18 authors reached a causal opinion in the 19 study? 20 MR. STOY: Objection to 21 form. Asked and answered. 22 THE WITNESS: You know, 23 again, sitting here right now, I 24 cannot say yes, it was a study</p> <p>Page 73</p> <p>1 done by, you know, Dr. X and Dr. Y 2 on such as topic. No, I cannot. 3 MR. STOY: Daniel, we've 4 been going a little over an hour, 5 let me know whenever there's a 6 good time to take a short break. 7 MR. NIGH: I think we can 8 take a break now. Ten minutes. 9 THE VIDEOGRAPHER: Off the 10 record. 10:15. 11 (Short break.) 12 THE VIDEOGRAPHER: We are 13 back on the record at 10:27 a.m. 14 BY MR. NIGH: 15 Q. Doctor, let's go ahead and 16 take a look at appendix B, your materials 17 relied upon list. This is part of your 18 expert report. I think that's Exhibit 4. 19 MR. NIGH: We don't need to 20 put it up on the screen. 21 BY MR. NIGH: 22 Q. And so as I run through 23 this, I want to make sure that I have 24 this accurate.</p>
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<p style="text-align: right;">Page 74</p> <p>1 You reviewed the medical 2 monitoring class action complaint, 3 correct? 4 A. Yes. 5 Q. And then you reviewed the 6 plaintiffs' memorandum of law in support 7 of the medical monitoring, correct? 8 A. Yes. 9 Q. And then you reviewed the 10 expert reports of Dr. Panigrahy and Dr. 11 Madigan, correct? 12 A. Yes. 13 Q. And did you review 14 Dr. Panigrahy's entire report or just 15 parts of his report? 16 A. I reviewed his entire 17 report. 18 Q. And did you review 19 Dr. Panigrahy's deposition testimony? 20 A. Yes. 21 Q. Did you review his whole 22 deposition transcript? 23 A. I believe I did read through 24 it, scan through it.</p>	<p style="text-align: right;">Page 76</p> <p>1 valsartan products. 2 That would be where the FDA 3 listed their testing results of valsartan 4 finished product, correct? 5 A. I believe so. I don't 6 remember offhand exactly what was there, 7 but since it says the FDA, I presume it 8 is the FDA testing results. 9 Q. And then you also reviewed 10 some studies, correct? 11 A. Yes. 12 Q. Those would have included 13 the Goodman study, correct? 14 A. Yes. 15 Q. And the Hidajat study? 16 A. Yes. 17 Q. And the Loh study? 18 A. Yes. 19 Q. And the Song study? 20 A. Yes. 21 Q. And the Snodin study? 22 A. Yes. 23 Q. And the Zheng study, 24 correct?</p>
<p style="text-align: right;">Page 75</p> <p>1 Q. And how about Dr. Madigan's 2 deposition testimony? Did you review 3 that? 4 A. Yes. 5 Q. Did you review his whole 6 transcript? 7 A. Yes, I scanned through it at 8 least. 9 Q. And then it also looks here 10 as if you have data. And you can see a 11 bunch of Bates numbers, APL-MDL2875, on 12 down, and TEVA. 13 Would those be valsartan 14 testing results by defendants? 15 A. Yes. 16 Q. So those would be in 17 spreadsheets or other documents that 18 demonstrate the amount of NDMA or NDEA in 19 API or finished products that the 20 defendants tested, correct? 21 A. Yes. 22 Q. And then on the next page, 23 you have this link to U.S. Food and Drug 24 Administration laboratory analysis of</p>	<p style="text-align: right;">Page 77</p> <p>1 A. Yes. 2 Q. And that Zheng study, that's 3 the Zheng study in regards to pancreatic 4 cancer, and in there they listed results 5 related to NDMA, correct? 6 A. Yes. 7 Q. Did you look for any 8 additional studies that have been 9 published since the time that Madigan and 10 Panigrahy gave their opinions? 11 A. I did not. That was beyond 12 the scope of what I was asked to do. 13 Q. Okay. So you wouldn't be 14 aware of whether or not there's any other 15 studies that show increased risk of liver 16 cancer in terms of additional amounts of 17 NDEA in a person's diet, correct? 18 MR. STOY: Objection. Form. 19 Scope. 20 THE WITNESS: So again, I 21 did not do a literature review. 22 And did you say NDEA -- 23 BY MR. NIGH: 24 Q. Yes.</p>

<p style="text-align: right;">Page 78</p> <p>1 A. -- or ND --</p> <p>2 Okay. So, yeah, that was</p> <p>3 beyond the scope of what I was asked to</p> <p>4 do.</p> <p>5 And so I am not aware of any</p> <p>6 other studies that were performed looking</p> <p>7 at any association between NDEA and</p> <p>8 increased cancer risk.</p> <p>9 Q. And other than the studies</p> <p>10 listed here and any other studies that</p> <p>11 may have been listed in Dr. Madigan's</p> <p>12 expert report, you did not rely upon any</p> <p>13 other studies or consider other documents</p> <p>14 in forming your opinions, correct?</p> <p>15 MR. STOY: Object to the</p> <p>16 form.</p> <p>17 THE WITNESS: Yeah, I</p> <p>18 believe I did not consider any</p> <p>19 other documents beyond those that</p> <p>20 are in the list of documents</p> <p>21 considered as well as in Appendix</p> <p>22 B here.</p> <p>23 BY MR. NIGH:</p> <p>24 Q. You just said other than</p>	<p style="text-align: right;">Page 80</p> <p>1 your knowledge, it would be this list of</p> <p>2 materials relied upon and the additional</p> <p>3 studies cited in Madigan's report that</p> <p>4 you would have considered, correct?</p> <p>5 A. To the best of my knowledge,</p> <p>6 I believe that is correct.</p> <p>7 Q. Now, Dr. Ballman, do you</p> <p>8 have any experience setting up a medical</p> <p>9 monitoring program?</p> <p>10 MR. STOY: Objection.</p> <p>11 Scope.</p> <p>12 THE WITNESS: I was not</p> <p>13 asked to have set -- to evaluate</p> <p>14 that, but I do not have any</p> <p>15 experience setting up a medical</p> <p>16 monitoring program.</p> <p>17 BY MR. NIGH:</p> <p>18 Q. Do you have any experience</p> <p>19 administering a medical monitoring</p> <p>20 program?</p> <p>21 A. I do not have any experience</p> <p>22 administering a medical monitoring</p> <p>23 program.</p> <p>24 Q. Before you offered your</p>
<p style="text-align: right;">Page 79</p> <p>1 those in the list of documents</p> <p>2 considered. What are you referring to?</p> <p>3 A. Yeah, I may have</p> <p>4 misremembered.</p> <p>5 I thought that there was</p> <p>6 also a list of documents considered,</p> <p>7 which included things like, you know, all</p> <p>8 the studies in the Madigan report.</p> <p>9 And maybe I'm</p> <p>10 mis-remembering from what counsel had</p> <p>11 told me.</p> <p>12 Q. Okay. So other than the</p> <p>13 studies listed in Madigan's report, and</p> <p>14 the studies that you relied upon here in</p> <p>15 Appendix B, there wouldn't be any</p> <p>16 other -- anything else in a list of</p> <p>17 materials considered, correct?</p> <p>18 MR. STOY: Object to the</p> <p>19 form.</p> <p>20 THE WITNESS: To the best of</p> <p>21 my knowledge, from what I can</p> <p>22 remember, I think that is correct.</p> <p>23 BY MR. NIGH:</p> <p>24 Q. Okay. And to the best of</p>	<p style="text-align: right;">Page 81</p> <p>1 opinion here today, have you had any</p> <p>2 litigation experience with medical</p> <p>3 monitoring?</p> <p>4 A. I have not, no.</p> <p>5 Q. Do you know of any medical</p> <p>6 monitoring programs that have been</p> <p>7 approved by courts?</p> <p>8 A. That's outside of my</p> <p>9 expertise. I am not aware of any</p> <p>10 monitoring programs that have been</p> <p>11 approved by courts, so no.</p> <p>12 Q. Are you aware of any medical</p> <p>13 monitoring programs in the United States?</p> <p>14 MR. STOY: Object to the</p> <p>15 form.</p> <p>16 Is your question ever?</p> <p>17 MR. NIGH: Yeah.</p> <p>18 THE WITNESS: And now I'm</p> <p>19 struggling a bit, because I'm not</p> <p>20 exactly sure if there is a</p> <p>21 technical definition of a medical</p> <p>22 monitoring program.</p> <p>23 I am aware of screening</p> <p>24 programs that are endorsed by</p>

<p style="text-align: right;">Page 82</p> <p>1 various medical associations, such 2 as the recommendation for one to 3 undergo lung cancer screening and 4 things like that. 5 BY MR. NIGH: 6 Q. When you say screening 7 programs, what do you mean by that? 8 A. What I mean is that these 9 are programs that are meant to screen 10 individuals who are considered to be at 11 high risk for developing cancer. 12 Q. Are you aware of any 13 programs where -- for screening, where 14 people were exposed to substances? 15 MR. STOY: Object to the 16 form. 17 THE WITNESS: The lung 18 cancer screening program is based 19 upon people being exposed to 20 cigarette smoke, which I believe 21 is a substance. 22 BY MR. NIGH: 23 Q. Okay. Other than the -- 24 other than for smoking, are you aware of</p>	<p style="text-align: right;">Page 84</p> <p>1 or what I do. 2 BY MR. NIGH: 3 Q. Okay. Doctor, I want to 4 turn your attention to Page 7 of your 5 expert report. Actually, the bottom of 6 Page 6. 7 You write, "Even assuming, 8 however, that plaintiffs" -- that's where 9 I'm reading from. 10 "Even assuming however the 11 plaintiffs can obtain and utilize 12 pharmacy records in the manner described, 13 what they cannot do from the information 14 provided is identify whether the proposed 15 class members in fact consumed the 16 prescribed valsartan, and if so, whether 17 the consumed valsartan contained NDMA 18 and/or NDEA." 19 Do you see that? 20 A. Yes. 21 Q. And I'm going to start with 22 the "whether the proposed class members 23 in fact consumed their prescribed 24 valsartan."</p>
<p style="text-align: right;">Page 83</p> <p>1 any programs where people -- for 2 screening where people were exposed to 3 substances or carcinogens? 4 A. So again, this is outside of 5 my area of expertise. So off the top of 6 my head, I can't -- I can't name one, 7 because this is beyond what I do. 8 Q. I understand. So other than 9 smoking, it's your answer that you're not 10 aware of any other programs where people 11 are being screened that were exposed to 12 substances or carcinogens? 13 MR. STOY: Object to the 14 form. 15 THE WITNESS: Again, I -- I 16 mean, another thing that comes to 17 mind is I believe that people that 18 were exposed to radiation, there 19 were screening programs set up for 20 them at the end of World War II. 21 There may be other 22 substances, I just am not 23 personally aware of them. It's 24 outside of my realm of expertise</p>	<p style="text-align: right;">Page 85</p> <p>1 Is it your opinion that 2 there is no sufficient way for plaintiffs 3 to establish that proposed class members 4 consumed their prescribed valsartan? 5 A. So that statement is based 6 upon my experience in clinical trials 7 where we monitor patients quite closely 8 for adherence. And even in those 9 situations, it's pretty hard to ensure 10 that people took the medications that 11 they were prescribed to take. So that's 12 the basis of that comment. 13 Q. Well, in your experience in 14 clinical trials where you're monitoring 15 patients, how are you able to even 16 determine adherence? 17 A. So in those situations, 18 patients oftentimes are asked to give -- 19 to keep a drug log where they log in when 20 they have taken something. 21 But again, we have to take 22 it on faith that if they logged it in 23 that they truly did take it. 24 In some instances, we also</p>

<p style="text-align: right;">Page 86</p> <p>1 monitor pill counts where they are asked 2 to bring in their pill bottles at each 3 visit, and the pills are counted to make 4 sure that, you know, they -- the correct 5 amount is -- had been consumed. 6 And then we just ask 7 patients and assume that they would be 8 truthful in telling us if they actually 9 adhered to the regimen. 10 Q. Now, when you ask patients, 11 why would you assume that they would be 12 truthful in telling you that they 13 actually adhered to the regimen? 14 A. We don't know for sure, but 15 I mean, as you said it's very hard to 16 determine if someone has taken medication 17 or is adherent. But that's the best we 18 can do is to assume that people are going 19 to be truthful, like they are when they 20 go to the doctor and ask how much alcohol 21 they've consumed, that they will just 22 give us the right -- the truthful answer. 23 Q. Do you know how plaintiffs 24 could establish the proposed class</p>	<p style="text-align: right;">Page 88</p> <p>1 identify the lot number of the 2 prescription, and not all lots of 3 valsartan were recalled. 4 We'll deal with the 5 variation of the manufacturer later. 6 Okay? 7 A. Okay. 8 Q. Is it your opinion that for 9 valsartan pills made with ZHP API, that 10 not all the lots of valsartan were 11 recalled? 12 MR. STOY: Objection. 13 Beyond the scope. 14 THE WITNESS: That is beyond 15 the scope of what I was asked to 16 do. 17 I do not know, nor can I 18 form an opinion, as to whether or 19 not all the lots were recalled. 20 BY MR. NIGH: 21 Q. Well, your statement 22 actually says, "Not all lots of valsartan 23 were recalled." 24 So now I'm asking you for</p>
<p style="text-align: right;">Page 87</p> <p>1 members consumed their prescribed 2 valsartan? 3 A. That's beyond the scope of 4 what I was asked to do. So I -- off the 5 top of my head, I have no opinion or 6 thoughts as to how they might determine 7 that. 8 Q. The next part of your 9 statement says, "Whether the consumed 10 valsartan contained NDMA and/or NDEA." 11 Do you see that? 12 A. Yes. 13 Q. And then you go on to state, 14 "The NDC code does not identify the lot 15 number of the prescription. Not all lots 16 of valsartan were recalled, and not all 17 tested lots from the same manufacturer 18 contain the same levels of detected NDMA 19 or NDEA." 20 I'm going to focus your 21 attention to the first parts of this 22 statement, that whether the consumed 23 valsartan contained NDMA and/or NDEA and 24 your concerns that the NDC does not</p>	<p style="text-align: right;">Page 89</p> <p>1 valsartan made with ZHP API, do you have 2 no opinion for valsartan made with ZHP 3 API? 4 A. I have no opinion with 5 respect to that. It's beyond the scope 6 of what I was asked to do. 7 Q. Is that your opinion for 8 valsartan pills made with Mylan API? 9 A. Again, I cannot sort of 10 point to any manufacturer and say that, 11 you know, their particular lots were not 12 recalled. 13 However, I am aware that 14 lots were recalled in a staggered manner. 15 And so at some time -- 16 Q. How are you aware that lots 17 were recalled in a staggered manner? 18 A. I think probably through 19 discussion with -- 20 MR. STOY: I do want to just 21 caution you, Doctor, not to reveal 22 the content of any discussions 23 that you had with counsel for the 24 defendants.</p>

<p style="text-align: right;">Page 90</p> <p>1 But keeping that in mind, 2 you can continue answering the 3 question. 4 BY MR. NIGH: 5 Q. How are you aware that lots 6 were recalled in a staggered manner? 7 A. I believe it was in -- I 8 don't know what I can say and not say 9 that doesn't violate privilege 10 information. 11 Q. Let me ask you this way. 12 Other than through discussions with 13 counsel, are you aware that lots were 14 recalled in a staggered manner any 15 other -- from any other independent 16 source? 17 A. No. 18 Q. Is it your opinion that not 19 all lots of valsartan were recalled for 20 Hetero, for valsartan that was made with 21 Hetero API? 22 A. Again, I cannot answer that 23 with certainty. 24 As I mentioned I do not know</p>	<p style="text-align: right;">Page 92</p> <p>1 well as what the agents are that are in 2 the product, as well as what the size is 3 in terms of how the product was 4 distributed. And there are no lot 5 numbers in that information. 6 Q. Do you know how many lot 7 numbers make up an NDC code? 8 A. That's beyond my area of 9 expertise. 10 Q. Do you know how many batches 11 make up an NDC code? 12 A. Again, that is beyond the 13 area of my expertise, no. 14 Q. Which finished dose 15 manufacturers use Mylan API for valsartan 16 finished pills? 17 A. Again, that's beyond the 18 area of my expertise. 19 I do not know. 20 Q. Which finished dose 21 manufacturer use Hetero valsartan API for 22 valsartan finished pills? 23 A. I do not know. Beyond the 24 area of my expertise.</p>
<p style="text-align: right;">Page 91</p> <p>1 which manufacturers' lots were completely 2 recalled and which were not. 3 Q. Which finished dose 4 manufacturers used ZHP API for their 5 valsartan finished pills? 6 MR. STOY: Objection. 7 Beyond the scope. 8 THE WITNESS: That is beyond 9 the scope of my expertise, and I 10 cannot answer that because I just 11 do not know. 12 BY MR. NIGH: 13 Q. So to be clear, when you're 14 mentioning that not all lots of valsartan 15 were recalled and the NDC does not 16 identify the lot number of the 17 prescription and your criticism as to 18 whether the consumed valsartan contained 19 NDMA and/or NDEA impurity, you don't know 20 which finished dose manufacturers used 21 ZHP API for valsartan finished pills? 22 A. I personally do not know. 23 It's my understanding that 24 the NDC codes list the manufacturer as</p>	<p style="text-align: right;">Page 93</p> <p>1 Q. Which finished dose 2 manufacturer used Aurobindo API for 3 valsartan finished pills? 4 A. I do not know. It's beyond 5 the area of my expertise. 6 Q. For valsartan pills made 7 with ZHP API, have you seen any testing 8 demonstrating that no NDMA was found in 9 any lots? 10 MR. STOY: Objection. 11 Scope. 12 THE WITNESS: And again, can 13 you repeat the question? Because 14 there were a lot of, like, 15 qualifications or -- just please 16 repeat the question. 17 BY MR. NIGH: 18 Q. Sure. Sure for valsartan 19 pills made with ZHP API, have you seen 20 any testing demonstrating that no NDMA 21 was found in those pills? 22 MR. STOY: Same objection. 23 THE WITNESS: Again, that 24 was beyond the scope of what I was</p>

<p style="text-align: right;">Page 94</p> <p>1 asked to do.</p> <p>2 I was given a bunch of</p> <p>3 testing information, but I did not</p> <p>4 pour over it carefully.</p> <p>5 We could look at the</p> <p>6 spreadsheet to see if that indeed</p> <p>7 is the case. But off of the top</p> <p>8 of my head, I'm unable to answer</p> <p>9 that question.</p> <p>10 BY MR. NIGH:</p> <p>11 Q. For valsartan pills made</p> <p>12 with ZHP API, have you seen any testing</p> <p>13 demonstrating that no NDMA could be</p> <p>14 detected in those pills?</p> <p>15 MR. STOY: Objection. Asked</p> <p>16 and answered.</p> <p>17 MR. NIGH: It's a different</p> <p>18 question.</p> <p>19 THE WITNESS: Was the</p> <p>20 question -- did you say NDMA or</p> <p>21 NDEA?</p> <p>22 BY MR. NIGH:</p> <p>23 Q. NDMA each time. Let me ask</p> <p>24 it again.</p>	<p style="text-align: right;">Page 96</p> <p>1 answer as to which manufacturer.</p> <p>2 Q. Well, for valsartan pills</p> <p>3 made with ZHP API, have you seen any</p> <p>4 testing demonstrating that any pills had</p> <p>5 less than 96 nanograms of NDMA?</p> <p>6 A. Again, since I cannot answer</p> <p>7 the previous questions because I cannot</p> <p>8 remember what was in those spreadsheets,</p> <p>9 I cannot answer that question.</p> <p>10 Q. For valsartan pills made</p> <p>11 with ZHP API, have you seen any testing</p> <p>12 demonstrating that any pills did not have</p> <p>13 at least thousands or tens of thousands</p> <p>14 of nanograms of NDMA?</p> <p>15 MR. STOY: Objection to</p> <p>16 form. Scope.</p> <p>17 THE WITNESS: You know,</p> <p>18 again, this is beyond the scope of</p> <p>19 what I was asked to do.</p> <p>20 I did look at spreadsheets.</p> <p>21 I do not recall the levels that</p> <p>22 were reported in there.</p> <p>23 And so I cannot answer that</p> <p>24 question.</p>
<p style="text-align: right;">Page 95</p> <p>1 For valsartan pills made</p> <p>2 with ZHP API, have you seen any testing</p> <p>3 demonstrating that no NDMA could be</p> <p>4 detected in those pills?</p> <p>5 A. Yeah, I'm sorry. I thought</p> <p>6 that was the previous question, so I</p> <p>7 guess I'm confused.</p> <p>8 But, again, you know, I</p> <p>9 cannot say with certainty unless I look</p> <p>10 at the testing material that was provided</p> <p>11 to me, and assuming that the testing</p> <p>12 material provided to me is all the</p> <p>13 testing information that's available.</p> <p>14 Q. But as you sit here, you</p> <p>15 have -- you did review some testing,</p> <p>16 correct?</p> <p>17 A. Yes. I looked at those</p> <p>18 documents. But I do not recall which</p> <p>19 manufacturer, which API, which whatever,</p> <p>20 had levels, did not have levels, and so</p> <p>21 forth.</p> <p>22 I know there are some that</p> <p>23 did not have detectable levels. But</p> <p>24 again, off the top of my head, I cannot</p>	<p style="text-align: right;">Page 97</p> <p>1 BY MR. NIGH:</p> <p>2 Q. For valsartan pills made</p> <p>3 with ZHP API, have you reviewed any</p> <p>4 information that demonstrates that there</p> <p>5 were some lots that were not recalled?</p> <p>6 A. Again, that's beyond the</p> <p>7 scope of my expertise and what I was</p> <p>8 asked to do. So I do not know for that</p> <p>9 particular manufacturer whether there</p> <p>10 were some lots that were not recalled.</p> <p>11 Q. So when you give the opinion</p> <p>12 that not all lots of valsartan were</p> <p>13 recalled, you wouldn't know if that's</p> <p>14 true for specifically for ZHP, correct?</p> <p>15 MR. STOY: Object to the</p> <p>16 form.</p> <p>17 THE WITNESS: Right now,</p> <p>18 sitting here without looking at</p> <p>19 the information provided and not</p> <p>20 understanding whether I was</p> <p>21 provided all the information, I</p> <p>22 could not answer that question.</p> <p>23 Yes.</p> <p>24 BY MR. NIGH:</p>

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1 Q. For valsartan pills made
2 with Mylan API, have you seen any testing
3 demonstrating that no NDEA was found in
4 those pills?
5 MR. STOY: Objection. Form.
6 Scope.
7 THE WITNESS: Again, this is
8 a similar answer to as before.
9 I do not recall, sitting
10 here without looking at the
11 information, as to whether or not
12 I saw any lots that did not --
13 that were recalled or not recalled
14 or what the level of impurity was
15 measured with respect to NDEA for
16 Mylan. I just -- I just can't
17 answer that.
18 BY MR. NIGH:
19 Q. For valsartan pills made
20 with Mylan API, have you seen any testing
21 demonstrating that any pills had less
22 than 26.5 nanograms of NDEA?
23 A. Again --
24 MR. STOY: Same objection as

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1 before.
2 Sorry.
3 THE WITNESS: Sorry.
4 Again, this is beyond my
5 scope.
6 And as I have been saying, I
7 cannot say with certainty whether
8 or not there were any lots of the
9 tested information provided to me
10 that were under the stated level.
11 I do not even know if I was
12 provided all the testing
13 information.
14 BY MR. NIGH:
15 Q. For valsartan pills made
16 with Mylan API, have you reviewed any
17 information that demonstrates that there
18 were some lots of unexpired medication
19 that were not recalled?
20 A. Beyond my area of expertise.
21 And I cannot answer that.
22 Q. So when you give the opinion
23 that not all lots of valsartan were
24 recalled, what are you referring to?

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1 A. Again, it's my
2 understanding -- and you went through a
3 list of some, that there were cases that
4 some lots of valsartan were not recalled
5 for certain manufacturers.
6 I cannot say which
7 manufacturers at this time. I don't know
8 that.
9 Q. So when you say not all lots
10 of valsartan were recalled, you don't
11 know for which manufacturers that
12 statement would be true?
13 A. Sitting here right now, no,
14 I do not.
15 Q. When you make the opinion
16 that whether the consumed valsartan
17 contained NDMA and/or NDEA impurity, you
18 wouldn't know as to which manufacturers
19 that opinion would apply to, correct?
20 MR. STOY: Object to the
21 form.
22 THE WITNESS: Again, this is
23 outside my area of expertise. And
24 I did not review all the testing

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1 literature, nor the recall
2 information on these agents.
3 And so I could not tell you
4 at this point which lots may have
5 or may not have contained the
6 impurities.
7 BY MR. NIGH:
8 Q. Now, if every lot from a
9 manufacturer that they tested has NDMA
10 and/or NDEA, then your statement that the
11 NDC does not identify the lot number of
12 the prescription would not matter,
13 correct?
14 MR. STOY: Object to the
15 form. Incomplete hypothetical.
16 Beyond the scope.
17 THE WITNESS: So I'm trying
18 to see if I get the assumption
19 right.
20 So if I assume there is a
21 manufacturer for which all the
22 lots were recalled for that
23 particular manufacturer, and over
24 a given time period and so forth,

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1 then I guess the lot number would
2 not matter for that particular
3 manufacturer, assuming that it has
4 been shown that all the lots were
5 contaminated.
6 BY MR. NIGH:
7 Q. Now, I want to draw your
8 attention to the next part of your
9 statement where it says, "Not all tested
10 lots from the same manufacturer contain
11 the same levels of detected NDMA or
12 NDEA."
13 Do you see that?
14 A. Yes.
15 Q. Now, are you aware that
16 approved medical monitoring programs
17 commonly have potential varying levels of
18 individual exposure?
19 MR. STOY: Object to the
20 form.
21 THE WITNESS: Medical
22 monitoring plans are outside the
23 scope of my expertise. And I do
24 not know necessarily how medical

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1 monitoring plans are formed. And
2 that was outside of what I was
3 looked at to do.
4 BY MR. NIGH:
5 Q. Can you think of any
6 approved medical monitoring programs
7 where class members have potential --
8 where class members exposed to substances
9 did not have potential varying levels of
10 individual exposure?
11 MR. STOY: Objection to
12 form. Scope. Calls for a legal
13 conclusion.
14 THE WITNESS: Again, that's
15 outside the area of my expertise.
16 And I do not know the
17 medical monitoring literature. So
18 I, off the top of my head, cannot
19 give you a specific instance.
20 BY MR. NIGH:
21 Q. In your report, you never
22 undertook any attempt to calculate means,
23 medians, midpoints, or ranges of the
24 amounts of NDMA or NDEA found for each

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1 manufacturer, correct?
2 A. That was beyond the scope of
3 what I was asked to do. And so I -- I
4 didn't see any reason to calculate those.
5 I did review some ranges
6 that were provided. I did see some
7 median values sometimes that were
8 provided.
9 Did I calculate those? I
10 did not, because I did not have the
11 necessary data in order to do that.
12 Q. In your expert report, you
13 did not attempt to assess what the means,
14 medians, midpoints, or ranges of NDMA
15 and/or NDEA exposure were for each NDC
16 code, correct?
17 A. I do not have the necessary
18 data in order to do such calculations.
19 So I did not do such calculations.
20 Q. And when you say that you
21 did not have the necessary data, you mean
22 that you were not provided with the
23 documents that could have allowed you to
24 do that calculation?

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1 A. Could you repeat what the
2 actual calculation was again?
3 Q. No, I'll strike that
4 question.
5 I next want to draw your
6 attention to Page 8 where you state,
7 "Plaintiffs assumed similar levels of
8 impurities in API products and finished
9 dose product."
10 Do you see that?
11 A. I'm sorry. Could you direct
12 my attention more where on the page?
13 Q. Page 8, Number 5. We put it
14 on the screen here too.
15 A. Okay.
16 Q. Your opinion was that --
17 A. Yes.
18 Q. -- "Plaintiffs assume
19 similar levels of impurities in API
20 product and finished dose product."
21 Do you see that?
22 A. Yes, I do.
23 Q. Now, how do you -- how did
24 you come up with the assumption that

<p style="text-align: right;">Page 106</p> <p>1 plaintiffs are assuming that?</p> <p>2 A. So that assumption came</p> <p>3 because I, again, looked at the lifetime</p> <p>4 cumulative thresholds that were proposed</p> <p>5 in the medical monitoring plan. And the</p> <p>6 information provided in that plan as to</p> <p>7 what provided the scientific basis for</p> <p>8 coming up with those thresholds would be</p> <p>9 found in the Panigrahy and -- I'll strike</p> <p>10 that.</p> <p>11 Q. I'm sorry. I don't know</p> <p>12 what you were striking. The whole</p> <p>13 answer?</p> <p>14 A. I'm starting my answer over.</p> <p>15 So yes, if I could strike the whole</p> <p>16 thing, that would be great.</p> <p>17 Q. Let me ask my question</p> <p>18 again. And then if you need some time to</p> <p>19 think about it, that's fine.</p> <p>20 Now, how did you come up</p> <p>21 with the assumption that plaintiffs are</p> <p>22 assuming similar levels of impurities in</p> <p>23 API product and finished dose product?</p> <p>24 A. I would have to look at the</p>	<p style="text-align: right;">Page 108</p> <p>1 that plaintiffs would have to assume</p> <p>2 values from the valsartan API as opposed</p> <p>3 to just relying on the FDA's finished</p> <p>4 dose testing levels?</p> <p>5 A. I don't think I assumed that</p> <p>6 they would have to use the API.</p> <p>7 As I said, I would need to</p> <p>8 look at the medical monitoring proposal</p> <p>9 to see what they actually used.</p> <p>10 I do not think that I</p> <p>11 assumed that they needed to use the API</p> <p>12 versus needed to use the FDA levels in a</p> <p>13 finished product.</p> <p>14 Q. Well, if plaintiffs used the</p> <p>15 FDA's finished testing -- the FDA's</p> <p>16 finished product testing levels, then</p> <p>17 this statement about the plaintiffs</p> <p>18 assuming similar levels of impurities in</p> <p>19 API product as finished dose product</p> <p>20 would be irrelevant, correct?</p> <p>21 MR. STOY: Objection to</p> <p>22 form. Argumentative.</p> <p>23 THE WITNESS: Again, I'm</p> <p>24 saying I don't know off the top of</p>
<p style="text-align: right;">Page 107</p> <p>1 medical monitoring report, because in</p> <p>2 Table 1, I -- I assumed that -- on the</p> <p>3 basis of what was in the APIs. And I'm</p> <p>4 not sure if that came from the actual</p> <p>5 medical monitoring proposal or not.</p> <p>6 Q. Did you review the</p> <p>7 deposition transcripts where Madigan</p> <p>8 and/or Panigrahy were presented with the</p> <p>9 finished product testing levels and</p> <p>10 answered questions in regards to finish</p> <p>11 product testing levels as demonstrated by</p> <p>12 the FDA?</p> <p>13 A. I've stated that I have read</p> <p>14 their depositions, but I do not, off the</p> <p>15 top of my head, recall instances of</p> <p>16 questions and answers regarding the</p> <p>17 finished products.</p> <p>18 Q. Why is it that you feel that</p> <p>19 plaintiffs would have to assume values</p> <p>20 from the valsartan API as opposed to just</p> <p>21 the FDA's finished testing levels?</p> <p>22 A. Could you please ask the</p> <p>23 question again?</p> <p>24 Q. Why is it that you believe</p>	<p style="text-align: right;">Page 109</p> <p>1 my head what the plaintiffs</p> <p>2 assumed without checking what is</p> <p>3 in the medical monitoring plan,</p> <p>4 which off of the top of my head</p> <p>5 right now, I cannot recall what</p> <p>6 they proposed.</p> <p>7 BY MR. NIGH:</p> <p>8 Q. When you make the statement</p> <p>9 that plaintiffs assume no variability of</p> <p>10 NDMA and/or NDEA impurity levels for the</p> <p>11 same manufacturer, what is the basis for</p> <p>12 that statement?</p> <p>13 A. When I looked at the testing</p> <p>14 data that was provided to me, I saw</p> <p>15 variability between the different lots.</p> <p>16 So that means that there was variability</p> <p>17 within the manufacturer.</p> <p>18 Q. Okay. So if there's</p> <p>19 variability within a manufacturer, why is</p> <p>20 it your -- why is it your opinion that</p> <p>21 the plaintiffs assume no variability in</p> <p>22 NDMA and/or NDEA impurity levels for the</p> <p>23 same manufacturer?</p> <p>24 A. Because when I looked at the</p>

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1 medical monitoring report proposal and
2 looked at the lifetime cumulative
3 thresholds that were proposed, they were
4 only proposed on the basis of a
5 manufacturer, and they were not on the
6 basis of a manufacturer and lot number.
7 Q. Did you consider any other
8 assumptions that the plaintiffs may have
9 made in terms of assessing variability as
10 opposed to plaintiffs assuming no
11 variability in NDMA and/or NDEA impurity
12 levels for the same manufacturer?
13 MR. STOY: Object to the
14 form.
15 THE WITNESS: That was
16 beyond the scope of what I was
17 asked to do.
18 I was just trying to, the
19 second part of my charge was to
20 try to -- well, the first part in
21 general is to understand if there
22 is evidence to support the use of
23 the proposed thresholds. And
24 there was only one threshold given

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1 per each manufacturer.
2 And so the simplest
3 assumption to make, Occam's Razor,
4 is that -- to assume that within a
5 manufacturer, there is no
6 variability; otherwise, there
7 would be thresholds on the basis
8 of the lot numbers.
9 BY MR. NIGH:
10 Q. You just said that would be
11 the simplest assumption. But you didn't
12 make any other potential assumptions as
13 to what the plaintiffs may have assumed
14 in terms of variability with NDMA and/or
15 NDEA impurity levels for the same
16 manufacturer, correct?
17 MR. STOY: Object to the
18 form.
19 THE WITNESS: So again, you
20 know, in science, if one proposes
21 a threshold, and to be
22 scientifically rigorous, it should
23 be pretty clear as to what the
24 basis is of that threshold.

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1 And so I don't think it's my
2 responsibility to make other
3 assumptions that are necessary in
4 order to explain why the
5 plaintiffs decided to use one
6 threshold per manufacturer.
7 And I did say what
8 assumption I assumed in order for
9 those thresholds to be valid.
10 BY MR. NIGH:
11 Q. So when you give the
12 statement, "Plaintiffs assume no
13 variability in NDMA and/or NDEA impurity
14 levels for the same manufacturer, you
15 actually mean that you assumed that
16 plaintiffs assumed no variability in NDMA
17 and/or NDEA impurity levels for the same
18 manufacturer, correct?
19 MR. STOY: Object to the
20 form.
21 THE WITNESS: So on the
22 basis that there was one threshold
23 per manufacturer, the assumption
24 is that there would be no

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1 variability within the
2 manufacturer.
3 BY MR. NIGH:
4 Q. That's the assumption that
5 you made, correct?
6 A. I don't know what other
7 assumption to make for those thresholds
8 to make sense, because if someone took a
9 lot that had no NDMA in it, let's say
10 from one of the manufacturers for the
11 given length of time that's stated as
12 part of the threshold, that threshold
13 wouldn't make sense versus someone that
14 took a lot, that had an immense amount.
15 So I just don't know what
16 other assumption could have been made.
17 And I welcome -- yeah.
18 Q. Now, you say that because if
19 someone took a lot that had no NDMA in
20 it.
21 But my understanding is you
22 don't have any knowledge, as you sit here
23 today, as to which manufacturers that
24 would be true for, correct?

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1 A. I have no --
2 Q. Or impossible?
3 MR. STOY: Object to the
4 form.
5 THE WITNESS: As I sit here
6 today, that is correct. I cannot
7 name manufacturers for which that
8 might be the case.
9 But I believe there are
10 manufacturers for which there was
11 no NDMA detected in the -- in
12 their product.
13 BY MR. NIGH:
14 Q. Okay. I want to turn your
15 attention -- we're going to stay on
16 Page 8.
17 And in reading your opinion,
18 you state for Number 5, you state, "The
19 thresholds in Table 1 further implicitly
20 assume the levels of impurity and effects
21 of valsartan API are the same as what
22 would be found in the finished dose
23 products, which is the valsartan tablet
24 that is consumed by an individual."

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1 You later put, "Reviewing
2 the manufacturers' testing data, it is
3 clear this is not the case. For example,
4 for Aurobindo valsartan 320-milligram
5 lot, packing batch number" -- and you
6 give a batch number -- "the amount of
7 NDEA detected in the API batch was 0.96
8 micrograms, and the amount detected in
9 the corresponding finished product batch
10 was .048 micrograms, which is a twofold
11 reduction in the level of impurity."
12 Do you see that?
13 A. Yes.
14 Q. And then you say, "This is
15 not an isolated case, but in general,
16 there appear to be lower levels of
17 impurity in the finished product tablet
18 that would be consumed compared to the
19 API."
20 Do you see that?
21 A. Yes.
22 Q. And then below, you list
23 testing documents.
24 Do you see that?

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1 A. Yes.
2 Q. Now, other than --
3 A. Sorry. Clarification,
4 please.
5 Do you mean the footnote?
6 Q. Yes.
7 A. Yes.
8 Q. It's actually Footnote 9,
9 not Footnote 8.
10 Right? Is it Footnote 9?
11 A. Yes, I believe so.
12 Q. And so other than for
13 Aurobindo, do you know if there are any
14 other manufacturers where you're seeing a
15 lower amount of NDEA that's generally
16 detected in the finished dose batch
17 compared to the API batch?
18 A. Without being able to look
19 at those documents at this time, I cannot
20 state with certainty what any other
21 manufacturer might be.
22 Q. So you only hold this
23 opinion for Aurobindo at this time?
24 MR. STOY: Object to the

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1 form. Misstates testimony.
2 THE WITNESS: That's not
3 what I said.
4 I said without being able to
5 review the documents that are
6 cited, off the top of my head I
7 cannot, with certainty, give you
8 another example.
9 BY MR. NIGH:
10 Q. Your wording says, "This is
11 not an isolated case, but in general
12 there appear to be lower levels of
13 impurity in the finished product tablet
14 that will be consumed compared to the
15 API."
16 Do you see that?
17 A. Yes.
18 Q. Other than Aurobindo, which
19 other manufacturers do you believe this
20 statement to be true for?
21 A. As I stated, that without
22 being able to -- and I'm happy to review
23 all of those spreadsheets, if you want.
24 I'm not able to name if

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1 there's another case where this is true.
2 MR. NIGH: Okay. Let's take
3 a look at LP 1779.
4 (Document marked for
5 identification as Exhibit
6 Ballman-5.)
7 BY MR. NIGH:
8 Q. I'm going to show you some
9 testing numbers for Mylan.
10 MR. NIGH: This will be
11 marked Exhibit 5.
12 BY MR. NIGH:
13 Q. And you have cited here
14 testing levels for Mylan in your expert
15 report, correct?
16 A. Yes, that's part of the
17 Footnote 9.
18 Q. And that Footnote 9 --
19 MR. NIGH: Hold on. If we
20 can go back to that first
21 paragraph, that first -- you just
22 had it on the screen.
23 BY MR. NIGH:
24 Q. This is the slip sheet for

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1 this document. Do you see it says
2 MYLAN-MDL2875-00895544?
3 A. Yeah, I'm waiting for it to
4 come into my documents here. Sorry.
5 Q. No problem. Let me know
6 when you have that.
7 A. Okay. It just came up.
8 Q. Do you see that Bates number
9 at the bottom right corner?
10 A. Yes, I see that.
11 Q. And then if we take a look
12 at the spreadsheet, turning to the next
13 page. Now, it's pretty small here, but
14 if you can take a look at -- hold on one
15 second.
16 MR. NIGH: There should be
17 an Excel version of this that you
18 can use, not this PDF. It looks
19 like it's cutting off some of the
20 columns we need.
21 TRIAL TECH: Okay. One
22 second, I'll check it.
23 MR. NIGH: I want to make
24 sure that the witness has the

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1 Excel spreadsheet as well.
2 TRIAL TECH: Spreadsheet is
3 in the shared file.
4 THE WITNESS: I see it.
5 MR. STOY: Just for the
6 record, are we replacing the PDF
7 with the Excel version as
8 Exhibit 5?
9 TRIAL TECH: I did, yes.
10 MR. STOY: Okay.
11 TRIAL TECH: Waiting for it
12 to load. One second.
13 BY MR. NIGH:
14 Q. Let's go, again, if you can,
15 NDMA content ppm finished dosage. You
16 can see it's Column I.
17 Do you see that?
18 A. Yes.
19 Q. And do you see Column K,
20 which is NDEA content ppm API?
21 A. Yes.
22 Q. Now, that would be -- those
23 two are referring to the parts per
24 million of NDEA in Mylan either in the

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1 API product or in the finished dose
2 product.
3 Do you see that?
4 MR. STOY: Object to the
5 form.
6 THE WITNESS: Yes, I believe
7 that's the case. I'm comparing I,
8 which is the finished dosage, to
9 K, which is the API.
10 BY MR. NIGH:
11 Q. Right. And the opinion that
12 you gave and cited to this document, was
13 that this is not an isolated case, but in
14 general, there appears to be lower levels
15 of impurity in the finished products,
16 compared to the API, right?
17 A. In general, there appears to
18 be lower levels of the impurity in the
19 finished -- in general, yes, that's what
20 I see there.
21 Q. Okay. Well, let's take a
22 look at this spreadsheet.
23 You see Row 28, we can see
24 the first test result on this spreadsheet

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1 in terms of order of rows.
2 The first one, .35 in Column
3 I.
4 Do you see that?
5 A. Yes.
6 Q. Now, Column K, it says, "Yet
7 to be analyzed."
8 Do you see that?
9 A. Yes.
10 Q. So we wouldn't be able to
11 make that comparison for this row,
12 correct?
13 A. Yes.
14 Q. Now, let's scroll down to
15 the next test result for -- in Column I
16 for NDEA content in the finished dose.
17 Do you see it shows
18 .46 parts per million?
19 A. Yes.
20 Q. And then in Column K, in the
21 API, it says .28, correct?
22 A. Yes, I see that.
23 Q. So for this result, it's
24 actually the reverse of what you had in

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1 your report. It's actually that the
2 amount of NDEA in the finished product is
3 actually higher than the amount of NDEA
4 in the API, correct?
5 A. I do not think my statement
6 as stated precludes this from happening.
7 It says in general. It does not say for
8 every case.
9 Q. Okay. Well, this first one
10 it didn't happen, right? There's more
11 NDEA in the finished product than in the
12 API, correct?
13 A. Yes.
14 Q. In Line 48, the second row
15 that we can see a comparison, there is
16 more -- .41, that's higher than .29,
17 correct?
18 A. Yes.
19 Q. So this is a second instance
20 of where there's actually more NDEA in
21 the finished products than the API,
22 correct?
23 A. Yes, that's correct.
24 Are we going to go through

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1 all the testing to make sure that the "in
2 general" statement -- because this is
3 just one spreadsheet. I mean, I know
4 like, on Line 60 --
5 Q. We're going to go through a
6 lot of them. We'll see the cumulative.
7 A. Okay.
8 Q. So the second one, more in
9 the --
10 MR. NIGH: Let's go ahead
11 and highlight each of those, the
12 .41 versus the .29. Highlight
13 yellow. Highlight yellow. Yep.
14 Row 46, yellow and yellow.
15 BY MR. NIGH:
16 Q. Again, those highlights
17 demonstrate thus far that the amount of
18 NDEA in the finished product is actually
19 higher than the amount of NDEA in the
20 API, correct?
21 A. Yes, that is correct. But
22 why are we skipping over the NDMA?
23 Q. Because for right now -- for
24 Mylan, is Mylan more of an NDEA

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1 contamination problem or more of an NDMA
2 contamination problem?
3 A. That's beyond -- I couldn't
4 say with certainty what more of a problem
5 is.
6 But for that statement, I
7 did not say that I was focusing on what
8 was more of a problem for an individual.
9 And if we look at NDMA,
10 there are instances where that statement
11 I provided is true.
12 Q. Do you think Number 46, that
13 even for NDMA, that BQL is lower than
14 .01?
15 A. I am not sure what BQL is.
16 Q. Okay. So for all of the --
17 so far that we can see on the screen, all
18 of the NDMA's suggest BQL for finished
19 product. So you don't actually know how
20 much NDMA is in the finished product,
21 correct?
22 A. Again, I'm not sure what BQL
23 is.
24 There is a BDL which may

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1 mean below detection level on Line 56.
2 And we can see that it's below -- 57 --
3 below detection in the finished product,
4 but there is some detected in the API.
5 Q. Is that --
6 A. So I mean, we can go
7 through --
8 Q. Is that how -- we will go
9 through this.
10 Is that how you -- what you
11 just explained to me, is that how --
12 would that formulate part of the basis of
13 your statement that there appear to be
14 lower levels of impurity in the finished
15 product compared to the API, because you
16 see a BDL in one line and you see a .01
17 in the other?
18 MR. STOY: Object to the
19 form.
20 THE WITNESS: So again, I'm
21 not sure exactly what BDL is, but
22 usually it means below detection
23 level.
24 So that means that it cannot

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1 be detected, whereas if a number
2 was given, it was detected.
3 So a number that's given
4 that was detected would be higher
5 than something that could not be
6 detected.
7 BY MR. NIGH:
8 Q. Okay. So that's your
9 opinion, is that if a number that was
10 given is detected, then that number would
11 be higher than something that could not
12 be detected, according to this
13 spreadsheet, right?
14 A. Again, that's outside of my
15 expertise. And I'm not saying with
16 certainty that that could be correct.
17 Q. I'm trying to understand the
18 basis of your opinion, that there appear
19 to be lower levels of impurity in the
20 finished product compared to the API.
21 Would this be one of the
22 bases of your opinions? If it says BDL
23 in one column, and the other column it
24 says .01, then you would say that the BDL

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1 is lower than the .01?
2 A. So when I read this, I
3 may -- I'm not sure if I was sloppy or
4 not. And I was referring to the
5 manufacturer for the specific example I
6 gave, or if really I meant everything.
7 I could have meant
8 everything, but then we'll have to go
9 through and look at all the documents
10 that I was provided to debate as to
11 whether or not it holds in general.
12 I agree that there are
13 instances where the finished product has
14 a higher level than does the API. I
15 agree that there are instances of that.
16 Q. My question was, would this
17 be one of the bases of your opinion where
18 it says -- of your opinion that there are
19 lower levels of API -- or lower levels of
20 impurity in the finished product compared
21 to the API? Would this be one of the
22 bases of your opinion where it says BDL
23 in one column, and in the other column
24 .01, and so that you would confer that to

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1 mean that the BDL is lower than the .01?
2 A. Again, without being able to
3 review exactly what BDL means and what
4 that lower level -- if it is below
5 detection level, what that threshold is,
6 I cannot say with certainty at this
7 point, without doing a bit more looking
8 at these documents.
9 Q. This is the spreadsheet that
10 you reviewed. This is what is attached.
11 Are you able to look at this
12 spreadsheet and give any indication as to
13 whether or not BDL is actually lower than
14 .01?
15 A. Again, you know, right now,
16 it was a while since I looked at this.
17 And as you are aware, there are many,
18 many spreadsheets with many, many
19 different numbers. And in fact, it takes
20 a while to even understand what each
21 column is without careful reading.
22 And, therefore, at this
23 time, I cannot state -- I cannot answer
24 that question.

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1 Q. Now, you did say below --
2 BDL stands for below detection level,
3 correct?
4 A. Again, I said that was --
5 that's what I'm assuming right now. But
6 I would have to check to make sure that
7 assumption is correct.
8 Q. Do you know what the
9 detection level is for this spreadsheet?
10 A. I believe I also stated that
11 I would have to take some time to look
12 and see what the threshold is for the
13 lower level of detection. So I do not --
14 with certainty, at this time, can state
15 what it is.
16 Q. Do you see that anywhere on
17 this spreadsheet where it says what the
18 detection level is?
19 A. Again, I was given more than
20 just this one spreadsheet.
21 You know, I just -- on this
22 spreadsheet right here, this page, I do
23 not see a definition of BDL.
24 Q. Okay. Let's go back to NDEA

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1 again. And let's keep going down. I
2 think you probably looked at more
3 columns.
4 Can you see that 49, do you
5 see it's .41 compared to .29? Again,
6 there's more NDEA in the finished product
7 than in the API?
8 A. Which line?
9 Q. Line 49.
10 MR. NIGH: Let's go ahead
11 and highlight this too.
12 THE WITNESS: Yes. For
13 those, that is correct.
14 BY MR. NIGH:
15 Q. And the next one, 53, line
16 53. Do you see it says .16 compared to
17 .16.
18 MR. NIGH: Let's highlight
19 that.
20 BY MR. NIGH:
21 Q. That also does not support
22 that there's more NDEA in the API than in
23 the finished product, correct?
24 A. You're correct for that one,

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1 yes.
2 Q. 54. Do you see .29, there's
3 more NDEA in the finished product than in
4 the API?
5 A. Yes.
6 Q. 55. Do you see there's more
7 NDEA in the finished product than in the
8 API?
9 A. Yes.
10 Q. 56, do you see there's more
11 NDEA in the finished product than in the
12 API?
13 A. Yes.
14 Q. 57, do you see there's more
15 NDEA in the finished product than in the
16 API?
17 A. Yes.
18 Q. 58, do you see there's more
19 NDEA in the finished product than in the
20 API?
21 A. Yes.
22 Q. 59, do you see there's more
23 NDEA in the finished product than in the
24 API?

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1 A. Yes.
2 Q. Now, can you look at this
3 spreadsheet as a whole and see that it's
4 actually the inverse for this
5 spreadsheet, that most of the products
6 tested here for Mylan had more NDEA in
7 the finished product than in the API?
8 MR. STOY: Object to the
9 form.
10 THE WITNESS: You know,
11 again, this is a very small
12 snippet that you had selected.
13 And I would like to look at all
14 the testing for the other NDMA of
15 all the spreadsheets that I looked
16 at.
17 I did not say this was
18 Mylan-specific.
19 In addition, I need to
20 understand what BQL -- I need to
21 refresh my memory -- and BDL is
22 for NDMA, because it may not apply
23 to NDMA.
24 BY MR. NIGH:

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1 Q. My question is, this is --
2 my question is, can you look at this
3 spreadsheet as a whole and see that it's
4 the actually the inverse for this
5 spreadsheet, that most of the products
6 tested here for Mylan had more NDEA in
7 the finished product than in the API?
8 I'm not asking about other
9 spreadsheets right now. I'll go to them
10 later. But do you see that for this
11 spreadsheet?
12 MR. STOY: Object to form.
13 Asked and answered.
14 THE WITNESS: Yeah, I
15 think -- you know, again, I'm just
16 going to say the same thing.
17 I mean, you know, as I
18 said -- and I haven't gone
19 through -- we haven't gone through
20 every single number. We haven't
21 tabulated it up.
22 And this is just one small
23 snippet of all the data that were
24 provided in terms of testing.

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1 We're not analyzing what's going
2 on with NDMA.
3 But yes, for the small cases
4 that you have pointed out in this
5 spreadsheet -- we didn't even go
6 through the whole thing -- I do
7 agree that in this case for that
8 small snippet, it appears that
9 in -- the finished product, has a
10 higher NDM -- no, NDEA than does
11 the API.
12 BY MR. NIGH:
13 Q. I asked you for this
14 spreadsheet. You can look at the whole
15 spreadsheet. Not just what I've
16 highlighted. There's not that many rows.
17 So you can actually look at it, I think,
18 as a statistician and see that for most
19 of the rows, more of the rows, there's
20 higher amounts of NDEA in the finished
21 products than in the API, correct?
22 MR. STOY: Objection to the
23 form.
24 THE WITNESS: I guess where

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1 I'm struggling is, you are
2 challenging my "in general."
3 And we're just looking at a
4 small snippet of data where it
5 appears not to hold for the in
6 general.
7 And I'm saying that I need
8 to look at everything, including
9 the NDMA, since I did not call out
10 NDEA just in, you know, specific.
11 I mean, I did for the
12 example, but that wasn't my
13 intent. That was true for NDMA --
14 sorry.
15 I would have to look at all
16 the testing data and -- yes. I
17 would have to look at all the
18 testing data, and I'd have to
19 understand what BQL means and BDL
20 means in order -- you know, in
21 order to answer that in general.
22 But the snippet you showed
23 me right here on this spreadsheet,
24 I do agree that the NDEA in the

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1 finished product is higher than in
2 the API.
3 BY MR. NIGH:
4 Q. Okay. Let me ask my
5 question again. My question does not ask
6 anything about your general statement
7 right now. I'm just asking about this
8 spreadsheet. You can review this
9 spreadsheet. It's not many rows.
10 MR. NIGH: Let's scroll
11 down. Scroll down. Let's keep
12 scrolling.
13 BY MR. NIGH:
14 Q. There's only 122 rows. And
15 most of the rows don't even have testing
16 for NDEA in the finished product,
17 correct?
18 A. I'm not sure what blanks
19 mean.
20 Q. What do you think they meant
21 when you reviewed these testing data?
22 A. Again, I would have to go
23 through and review all the documents that
24 I was given in general to understand what

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1 exactly they meant.
2 You're right. They could
3 mean that they weren't tested.
4 Q. For those rows where you see
5 testing levels for finished product
6 versus testing levels for API on this
7 Mylan spreadsheet, most of the rows
8 actually demonstrate that there's higher
9 amounts of NDEA in the finished products
10 than there is in the API, correct?
11 MR. STOY: Objection. Asked
12 and answered.
13 Go ahead.
14 MR. NIGH: It's not
15 answered.
16 THE WITNESS: For the small
17 preselected thing that I did not
18 select, I agree with what you are
19 showing me here are instances
20 where more of the finished
21 product -- I'm sorry -- the
22 finished product contains higher
23 levels of NDEA than does the API.
24 BY MR. NIGH:

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1 Q. Let's go back to your expert
2 report.
3 MR. STOY: Daniel, before we
4 move on, would this be a decent
5 time to take a five-minute break?
6 MR. NIGH: Give me about
7 five minutes, and I think we'll be
8 at a good breaking spot.
9 MR. STOY: Okay.
10 BY MR. NIGH:
11 Q. Let's look at Page 9 of your
12 expert report.
13 MR. NIGH: If we can put
14 that up on the screen again. It's
15 Exhibit 5.
16 THE WITNESS: Yes, I'm
17 there. I'm sorry.
18 MR. NIGH: I just wanted to
19 put it up on the screen.
20 THE WITNESS: Oh.
21 MR. NIGH: If we can blow up
22 Footnote 9. And also from the
23 expert report, if we can blow up
24 that sentence that says, "This is

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1 not an isolated case, but in
2 general there appear to be lower
3 levels of impurity in the finished
4 product tablet that will be
5 consumed compared to the API."
6 Can you blow that up as
7 well.
8 TRIAL TECH: Yeah, if you
9 can just guide me to --
10 MR. NIGH: It's at the top
11 of Page 9. And then you see the
12 Footnote 9. Yep.
13 BY MR. NIGH:
14 Q. And so your footnote says,
15 "See example." And that's your examples
16 for supporting this statement, correct?
17 A. Yes, I believe I'm just
18 listing all the testing data.
19 Q. Now, for Mylan, do you see
20 any other documents other than
21 MYLAN-MDL2875-00895544?
22 A. I don't see any other
23 document that has Mylan in the title. So
24 I'm not sure if some of the other -- I

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1 don't know these titles intimately so as
2 to what manufacturer they are referring
3 to.
4 But if you say that's the
5 only Mylan, I will take that.
6 Q. Well, I'm asking you.
7 And let's go to Appendix B.
8 And you can see under data of Appendix B
9 for materials that you relied upon, it
10 again only has that same Mylan Bates
11 number, correct?
12 A. Yes. That's the only --
13 only thing with Mylan in the title.
14 Q. Well, as far as you recall,
15 you are not aware of any other -- for
16 Mylan, any other documents that you would
17 have reviewed upon that you can base the
18 statement that this is not an isolated
19 case, but in general there appear to be
20 lower levels of impurity in the finished
21 products compared to the API?
22 MR. STOY: Object to the
23 form.
24 THE WITNESS: So I don't

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1 believe my statement said that
2 this is true for one particular
3 manufacturer.
4 I think the footnote is
5 referring to everything.
6 And we haven't gone through,
7 like, the one where I pulled the
8 actual example from, to look the
9 at the differences there. We
10 haven't looked at the NDMA
11 differences.
12 But I believe that may be
13 the only Mylan testing document
14 that I have.
15 BY MR. NIGH:
16 Q. So for Mylan, it would not
17 be true that there appear to be lower
18 levels of impurity in the finished
19 product compared to the API, correct?
20 MR. STOY: Object to the
21 form.
22 THE WITNESS: Again, I
23 cannot state that with certainty
24 because there are other tabs in

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1 that spreadsheet that we should go
2 through. We haven't gone through
3 the NDMA.
4 So I cannot state that with
5 certainty.
6 The only thing that I can
7 state is the numbers we went
8 through together for NDMA -- or
9 NDEA, that statement does not
10 hold.
11 BY MR. NIGH:
12 Q. When you say the numbers
13 that we went through together, do you
14 mean that whole spreadsheet we looked at?
15 Because I scrolled all the way down to
16 Row 120. And I asked you about that
17 whole spreadsheet.
18 Isn't it generally true that
19 the levels of NDEA were higher in the
20 finished products than in the API? Do
21 you remember that?
22 A. Yes, for that spreadsheet.
23 But there are other spreadsheets in that
24 document as well.

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1 Q. Did you see that for those
2 other spreadsheets, that they actually
3 don't give you the comparison between
4 those two except for a couple of rows?
5 A. But there are ND -- yes, for
6 NDEA.
7 Q. NDEA. Right.
8 If you look at Tab 2,
9 let's -- do you have that document,
10 Tab 2 --
11 A. Yeah, I have -- yes.
12 Q. -- of what's been marked as
13 Exhibit 5?
14 A. Yes.
15 Q. You can see Tab 2, that's
16 titled valsartan HCTZ, right?
17 A. Yes.
18 Q. And you can see that for
19 Tab 2, there is not a single test result
20 for NDEA content, correct, in Column I?
21 MR. NIGH: Can we scroll all
22 the way down.
23 THE WITNESS: Wait. I'm
24 sorry, say your statement again.

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1 BY MR. NIGH:
2 Q. In Tab 2, which is the --
3 you said there are different tabs. So
4 we're going through them now. You can
5 see for valsartan HCTZ there is not a
6 single test result in Column I, so we
7 can't make the comparison, correct?
8 A. Are we talking about NDMA?
9 Because that's Column I.
10 Q. My apologies. Column J.
11 A. Yeah, there are no numbers
12 in that column.
13 Q. And for the third
14 spreadsheet, we can scroll through and we
15 can see that there are very few where the
16 comparison can actually be made, where
17 there are test results for Column I -- I
18 mean, test results for Column I and test
19 results for Column K, correct?
20 A. Okay. So I am scrolling
21 down.
22 My understanding, and I'm
23 sorry I'm not able to freeze the titles
24 of the columns. But Column I is the

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1 finished product. Column K is the API.
2 And when there are instances, there are
3 many instances in which there are no
4 numbers to compare.
5 But when there are, like on
6 220, it appears that the finished product
7 has a lower amount than the API.
8 Q. This comparison can only be
9 made in two spots in this entire
10 spreadsheet, correct, where you have
11 testing for NDEA in the finished product
12 and testing for NDEA in the API?
13 A. Yeah, I found one.
14 Q. Okay. A few rows down.
15 A. Yeah, I'm sorry. I believe
16 you said that there are two. I only
17 found one.
18 Q. Okay. Whether it's one or
19 two, it's the same statement, is that
20 there's really not much evidence in all
21 of these spreadsheets from Mylan that
22 there's more NDEA in the finished -- in
23 the API than there is in the finished
24 product, correct?

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1 MR. STOY: Object to the
2 form.
3 THE WITNESS: So again, you
4 know, I agree that the numbers
5 being reviewed right now for the
6 comparison for just on these
7 spreadsheets, which are Mylan for
8 NDEA, more often the finished
9 product had a higher dose than did
10 the API.
11 BY MR. NIGH:
12 Q. Okay. Now we've talked
13 about Mylan having higher amounts of NDEA
14 in the finished products than in the API.
15 And you gave some examples
16 of Aurobindo having higher amounts of
17 NDEA in the API than in the finished
18 products.
19 But other than Mylan and
20 Aurobindo, do you have an opinion
21 specific to manufacturer as to which
22 manufacturers had higher amounts of NDEA
23 and/or NDMA in their finished products
24 versus their API, or vice versa, higher

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1 amounts in their API versus their
2 finished products?
3 A. Without --
4 MR. STOY: Object to the
5 form.
6 I'm sorry. Go ahead.
7 THE WITNESS: Without going
8 through this exercise, which I
9 thought we were going to do, for
10 all the spreadsheets, at this time
11 I cannot call out, like, which
12 particular manufacturers this may
13 or may not be true for, as well as
14 for NDMA in getting definitions of
15 those quantities, which right now
16 I do not know what they are, off
17 of the top of my head.
18 So if we want to -- let's
19 continue and go through, we can
20 answer that, because I thought you
21 said that we were going to go
22 through more spreadsheets.
23 BY MR. NIGH:
24 Q. When we -- or when you made

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1 the statement -- tried to analyze that
2 there's more NDMA and/or NDEA in the API
3 than in the finished products, did you
4 tabulate and take a count as to looking
5 at all the spreadsheets collectively and
6 seeing if that statement were true?
7 A. I did not, like, do a
8 precise count. It was just looking at
9 the values, from what I remember.
10 And I don't think it changes
11 my conclusion that the implicit
12 assumption that the level of impurity in
13 the valsartan API formulation is the same
14 as the finished product.
15 And we also did not get into
16 the fact that there is one lifetime
17 cumulative threshold per manufacturer,
18 and it doesn't say if it's for NDMA or
19 NDEA.
20 Q. My question was very -- much
21 more limited. I didn't talk about the
22 things that we didn't ask.
23 I'm only asking, when you
24 made the statement, that statement that

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1 this is not an isolated case, but in
2 general there appear to be lower levels
3 of impurity in the finished product
4 compared to the API, and you cited some
5 examples for Aurobindo, did you actually
6 compare the other finished dose product
7 testing results for the other
8 manufacturers compared to their API
9 levels?
10 A. I cannot recall at this time
11 which ones I compared.
12 I did not do -- I do -- can
13 say that I did not do an explicit
14 enumeration of the -- which -- how many
15 times it was greater or how many times it
16 was less. It was more just looking at
17 them and seeing that, you know, more
18 often than not, it appeared to be the
19 case.
20 Q. Specifically for Mylan, is
21 it your opinion that there appear to be
22 lower levels of impurity in the finished
23 product compared to the API?
24 A. I cannot answer that for

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1 Mylan, because we have not gone through
2 the NDMA data.
3 Q. Specifically for ZHP, is it
4 your opinion that there appear to be
5 lower levels of impurity in the finished
6 product compared to the API?
7 A. If we can go through those
8 spreadsheets right now, I can answer that
9 definitively. Right now, I cannot
10 remember off the top of my head if that
11 is true or not.
12 Q. I'm trying to understand
13 what your opinion is.
14 Is it your opinion that you
15 don't have an opinion specifically for
16 ZHP?
17 MR. STOY: Object to the
18 form. Misstates her testimony.
19 THE WITNESS: Again, I'm
20 saying I cannot state with
21 certainty what I feel for a
22 particular manufacturer. And I
23 would have to go through and look
24 at the data to be able to say with

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1 certainty for a particular
2 manufacturer, because I looked at
3 many, many spreadsheets as to
4 whether or not that's the case.
5 BY MR. NIGH:
6 Q. Okay. Well, we don't have
7 to go through every spreadsheet right
8 now.
9 I can assume that you've
10 reviewed those spreadsheets.
11 I'm asking you, in terms of
12 your opinion, is it your opinion that for
13 ZHP, there appear to be lower levels of
14 impurity in the finished product compared
15 to the API?
16 A. And I'm saying that my
17 opinion was based on all the testing data
18 that I looked at, and I cannot make -- I
19 cannot tell you with certainty for a
20 particular manufacturer if that is true.
21 Q. So you don't have that
22 opinion for ZHP, correct?
23 A. My opinion is based upon
24 looking across all the testing data of

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1 all the manufacturers. And so I cannot
2 say -- I cannot say without looking at
3 the individual manufacturers what my
4 opinion is for an individual.
5 Q. For Hetero, is it your
6 opinion that for Hetero, there appear to
7 be lower levels of impurity in the
8 finished product compared to the API?
9 A. As I stated, my opinion was
10 based upon looking at all the testing
11 data across all the manufacturers, so I
12 cannot at this time without reviewing the
13 data tell you with certainty what I would
14 say for Hetero in isolation.
15 MR. NIGH: Let's go ahead
16 and take a break.
17 THE VIDEOGRAPHER: Off the
18 record at 11:53 a.m.
19 (Short break.)
20 THE VIDEOGRAPHER: We are
21 back on the record at 12:10 p.m.
22 BY MR. NIGH:
23 Q. Doctor, I want to turn you
24 to Page 10 of your expert report.

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1 I want to direct you to the
2 attention -- to the following statement:
3 It says, "If one employs the LCE
4 definition proposed by Dr. Madigan to the
5 occupational exposure studies, the LCE
6 would use the lower bound of NDMA daily
7 level in the highest group."
8 Do you see that?
9 A. Yes.
10 Q. Is it your understanding
11 that Dr. Madigan -- Dr. Madigan's
12 definition of LCE for the dietary studies
13 was that he would use the lower bound of
14 NDMA daily level in the highest group?
15 A. From what I remember, that
16 is the case. We can go ahead and look at
17 his report, and I can point out where I
18 think I took that from.
19 MR. NIGH: Let's go ahead
20 and attach that as an exhibit.
21 (Document marked for
22 identification as Exhibit
23 Ballman-6.)
24 MR. NIGH: We can pull this

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1 document down. This will be LP
2 1558. It will be marked as
3 Exhibit 6.
4 BY MR. NIGH:
5 Q. This is Dr. Madigan's expert
6 report.
7 Do you have this document as
8 well, Doctor?
9 A. Yeah, I just see it now.
10 Q. Okay. Where in
11 Dr. Madigan's report do you believe that
12 he gives the definition for LCE for
13 dietary studies to mean that he would use
14 the lower bound of NDMA daily level in
15 the highest group?
16 A. So if you go to Page 3,
17 Paragraph Number 8, on the -- I believe
18 it's the second-to-last sentence. "For
19 each study I compute the mean lifetime
20 cumulative exposure as the average number
21 of days from birth to study end
22 multiplied by the lower bound of the NDMA
23 or NDEA daily level in the highest
24 group."

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1 Q. Did Dr. Madigan compute any
2 other LCEs that you can see in this?
3 A. Can you say that again,
4 please?
5 Q. Did Dr. Madigan compute any
6 other LCEs for dietary studies other than
7 the lower bound of NDMA daily or NDEA
8 daily level in the highest group?
9 A. So I believe if we go to his
10 table, Number 1, there are instances
11 where he notes that it's also significant
12 for the second quintile, first quintile,
13 and gives LCEs for those. But that's an
14 exception from his original rule, is how
15 I took it.
16 Q. Okay. If we -- when you see
17 at the bottom, Page 7, you can see all
18 these asterisks.
19 Do you see that?
20 A. Yes.
21 MR. NIGH: Let's blow those
22 up.
23 BY MR. NIGH:
24 Q. Those are other LCE that

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1 he's calculated, right?
2 A. Yes. I believe that's what
3 I said.
4 Q. What do you think he's
5 referring to when he puts for the first
6 asterisk here, "LCE equals
7 3,506 micrograms"? What do you think --
8 A. So that --
9 Q. -- that LCE is? What does
10 that mean?
11 MR. STOY: Object to the
12 form.
13 THE WITNESS: So I'm pretty
14 sure I matched it.
15 What he did is he deviated
16 from his general rule of using the
17 highest group, and he did it for
18 the second quintile, because he
19 observed that that was
20 statistically significant even at
21 that level.
22 So he computed an LCE in
23 that case using the lower bound of
24 the second quintile.

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1 BY MR. NIGH:
2 Q. So it's your belief that his
3 definitions fully encompassed -- his
4 definition of LCE is simply the average
5 number of days from birth to study end
6 multiplied by lower bound of NDMA or NDEA
7 daily level in the highest group, as seen
8 on Page 3?
9 A. That's what he states for
10 each study, that's how he computed a mean
11 lifetime cumulative exposure.
12 I would take that as a
13 definition. That's how statisticians
14 sort of define what they do.
15 Q. Do you see Page 7, that for
16 every single one of the dietary studies,
17 he gives a base dose microgram and then
18 an LCE microgram?
19 Do you see that?
20 A. Yes.
21 Q. And it says base high dose
22 microgram and then LCE microgram.
23 Do you see that?
24 A. Yes. Yes.

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1 Q. So for each study, he did
2 calculate the LCE for the base high dose
3 microgram for each study, correct?
4 A. Yes, he calculated an LCE,
5 as we see in that column. Every column
6 has a number.
7 Q. But then, in addition -- so
8 he followed his instruction on Page 8,
9 where he says, "For each study I compute
10 the mean lifetime cumulative exposure as
11 the average number of days from birth to
12 study."
13 So he did that for each
14 study. He followed that instruction,
15 correct?
16 A. Yes.
17 Q. But he also calculated LCEs
18 for lower quintiles, quartiles, or
19 tertiles, correct?
20 A. Yes. But that wasn't his
21 definition of how he was going to
22 calculate an LCE. This is a deviation
23 from that. And he doesn't note that.
24 Q. Can't you see that in his

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1 statement in eight that it's not actually
2 a definition of LCE, but rather what he's
3 doing, the steps he's taking?
4 MR. STOY: Object to the
5 form. Mischaracterization.
6 THE WITNESS: So again, as a
7 statistician reading this, knowing
8 that it's written by another
9 statistician, he -- to me, he is
10 defining what he -- what an LCE
11 is.
12 And that was his definition
13 on Page 3.
14 However, in some instances,
15 when a lower quintile comparison
16 had a statistically significant
17 result, and usually only in those
18 instances does he deviate from
19 that general definition.
20 BY MR. NIGH:
21 Q. Okay. Do you not see how
22 that could be read that -- as not just a
23 general definition, but rather a step
24 that he took?

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1 MR. STOY: Object to the
2 form.
3 BY MR. NIGH:
4 Q. In Number 8?
5 A. That's not how I would read
6 it, is all I'm saying.
7 In my opinion, that is what
8 he meant by a definition, and then he
9 made some deviations from it.
10 Q. Yeah, but I'm asking you,
11 can't you see, as you read it now that
12 I'm pointing it out, that that could be
13 just him explaining a step, not actually
14 defining what LCE means?
15 MR. STOY: Objection. Form.
16 Asked and answered.
17 THE WITNESS: Again, it
18 says, "For each study I compute
19 the mean lifetime cumulative
20 exposure as."
21 To me, for each study, this
22 was the definition that he was
23 going to apply for what the LCE
24 is.

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1 Having said that, he did
2 make some deviations, and in
3 instances where he found a
4 statistically -- or the report had
5 a statistically significant
6 association at lower levels, he
7 then deviated from this
8 definition.
9 BY MR. NIGH:
10 Q. Did you review his testimony
11 when he discussed what an LCE is and
12 defined it in deposition?
13 A. I did review his testimony.
14 I do not know how he defined LCE in his
15 deposition, offhand. I don't know.
16 Q. So you wouldn't know that he
17 actually didn't define LCE as only -- as
18 being for the highest group?
19 MR. STOY: Object to the
20 form.
21 THE WITNESS: Again, I was
22 asked to review his expert report
23 as the basis for the computed
24 lifetime cumulative thresholds.

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1 And it referred to his expert
2 report.
3 It did not refer to his
4 testimony. So if he changed the
5 definition, I used the definition
6 in the expert report as what I was
7 asked to do.
8 MR. NIGH: Let's pull up
9 Page 3 again where you've got
10 this -- where you believe there is
11 a definition of LCE. Let's pull
12 that up.
13 BY MR. NIGH:
14 Q. When you see, "For each
15 study I compute the mean lifetime
16 cumulative exposure" --
17 MR. NIGH: And let's
18 underline the word "as." No,
19 don't highlight that please. Just
20 underline the word "as."
21 And underline the word "in,"
22 the highest group, the word "in."
23 Right before "the highest group,"
24 the word "in."

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1 BY MR. NIGH:
2 Q. Okay. Do you see those two
3 words, "as" and the word "in"?
4 A. Yes.
5 Q. How do you know that the
6 definition doesn't end before the word
7 "in"?
8 A. Because that would be very
9 strange, because this is how one makes
10 the definition.
11 It's the entire thing. It
12 says "in the highest group."
13 So one would read that as a
14 statistician that he's taking what the
15 bound is, the lower bound for the highest
16 group, as that's what he's going to use
17 in his computation for the LCE.
18 Q. So when you see that there's
19 the words LCE for all these other
20 quartiles, how does that fit in with this
21 definition?
22 A. Say that again, please.
23 Q. When you see the words LCE,
24 like we saw all the asterisks and all the

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1 other LCEs, how does that fit in with
2 this definition?
3 A. A deviation from this
4 definition, as I stated.
5 Q. So that's the way in which
6 you would interpret it, is a deviation,
7 as opposed to the definition of LCE
8 simply being the average number of days
9 from birth to study end multiplied by the
10 lower bound of NDMA or NDEA, hard stop?
11 A. Yeah, because it would have
12 to be in what.
13 Because that would be
14 ambiguous.
15 Q. Okay.
16 A. There are many lower bounds.
17 Q. Well, nonetheless, you can
18 see that for each of the lower bounds --
19 there are many lower bounds, and that's
20 where we're going to go to Page 7.
21 MR. STOY: Is there a
22 question pending?
23 MR. NIGH: No, I'm going to
24 go to Page 7 here.

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1 BY MR. NIGH:
2 Q. So there are -- as you say,
3 there are many lower bounds, correct?
4 A. Well, what I meant is when
5 one chunks the data into groups such as
6 tertiles, quartiles, or quintiles as was
7 done in the underlying studies, what
8 Dr. Madigan was doing was to be clear as
9 to which lower bound he was using of
10 which group, because there are numerous
11 groups. And he says the highest group in
12 that definition.
13 Q. Okay. That's how you've
14 chosen to define it. I think we looked
15 at that on the screen. That's how you
16 chose to define it, as the "in," correct?
17 A. As a -- yes.
18 MR. STOY: Object to the
19 form.
20 Hang on. Object to the
21 form.
22 Go ahead.
23 THE WITNESS: As a
24 statistician, who -- who reads,

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1 you know, stuff from other
2 statisticians, I don't believe
3 it's just how I would interpret
4 that.
5 I believe any other
6 statistical expert would also
7 interpret it that way.
8 BY MR. NIGH:
9 Q. But you didn't review his
10 testimony to see how he actually
11 interpreted LCEs, correct?
12 A. Again, it --
13 MR. STOY: Object to the
14 form.
15 I'm sorry. Go ahead.
16 THE WITNESS: Again, I was
17 asked to look at -- again, in the
18 medical monitoring plan, the
19 definition or the basis for the
20 stated lifetime cumulative
21 thresholds refers to the expert
22 report of Dr. Madigan. It does
23 not refer to his deposition
24 transcription.

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1 Therefore, that is what I
2 used, because I was asked to see
3 how those lifetime cumulative
4 thresholds, what evidence there is
5 for those by looking at the expert
6 reports -- by -- I'm sorry.
7 I was asked to -- evidence
8 for those, and the medical
9 monitoring plan referred to those
10 expert reports.
11 BY MR. NIGH:
12 Q. Okay. Nonetheless, he uses
13 the letters "LCE" for lower quartiles,
14 quintiles, or tertiles, not just the
15 highest tertile, for both the dietary
16 studies and the occupational exposure
17 studies, correct?
18 A. So he uses the highest
19 group, not highest tertiles. So if the
20 groups were in tertiles, then it would be
21 the highest tertiles. If the groups were
22 in quintiles, it would be the highest
23 quintiles, so the highest group.
24 Q. No, he actually puts the

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1 letters "LCE" when referring to lower
2 groups both in dietary studies and the
3 Hidajat study, correct?
4 A. He uses that -- those
5 letters, that is correct. And I'm saying
6 he's deviating from his general
7 definition of how he computed the LCE.
8 Q. Okay. You've decided to
9 make that determination blind to anything
10 that he had clarified in his deposition
11 testimony, correct?
12 MR. STOY: Objection.
13 Argumentative.
14 THE WITNESS: So again, I
15 was asked to look at the medical
16 monitoring plan and the proposed
17 LCTs. And when I looked at that,
18 the -- for evidence to support
19 those LCTs, and when I looked at
20 the medical monitoring part, it
21 says based on the expert reports.
22 It did not say based on a
23 deposition transcription.
24 BY MR. NIGH:

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1 Q. So you -- even though you
2 reviewed Dr. Madigan's testimony, you
3 didn't feel it was important to see how
4 he defined LCEs in his deposition
5 testimony because of that, right?
6 MR. STOY: Object to form.
7 Misstates her testimony.
8 THE WITNESS: Again, I was
9 charged with looking at the
10 medical monitoring plan, looking
11 at what the proposed LCTs were and
12 determining whether or not there
13 was evidence to support those.
14 What was referred to with
15 how those LCTs were derived, the
16 only things that were cited were
17 the expert reports of
18 Dr. Panigrahy, as well as Dr.
19 Madigan.
20 It did not say as well as
21 their testimony.
22 BY MR. NIGH:
23 Q. I understand that statement.
24 So you took that statement to believe,

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1 then, that you did not have to consider
2 Dr. Madigan's clarifications in his
3 deposition testimony; is that accurate?
4 MR. STOY: Form objection.
5 THE WITNESS: So I would
6 have to see if there were
7 clarifications, because off of the
8 top of my head, I don't remember
9 his testimony.
10 And again, that -- his
11 testimony was not cited in what
12 the basis were for coming up with
13 the LCTs.
14 BY MR. NIGH:
15 Q. You keep coming up -- coming
16 back to his testimony not cited for the
17 basis for his coming up with the LCTs. I
18 keep asking you about the deposition
19 testimony.
20 It sounds to me like you're
21 saying because it's not cited in Kaplan's
22 report -- is that what you're referring
23 to?
24 MR. STOY: Object to the

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1 form of the question.
2 Go ahead.
3 THE WITNESS: What I was
4 saying was, it was not cited in
5 the medical monitoring plan for
6 the basis of forming the LCTs.
7 BY MR. NIGH:
8 Q. Okay. Since it's not cited
9 in the medical monitoring plan for the
10 basis of forming LCTs, is that the reason
11 you would not look at the deposition
12 testimony?
13 MR. STOY: Object to the
14 form.
15 THE WITNESS: So I believe I
16 stated that I had looked at the
17 deposition testimony.
18 And I think I've also stated
19 that I don't recall him changing
20 the definition of the LCE or
21 clarifying it. He could may well
22 have.
23 But again, I didn't think it
24 was relevant because that was not

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1 cited as the basis for determining
2 the LCTs in the medical monitoring
3 report.
4 BY MR. NIGH:
5 Q. I want to see if I have your
6 testimony accurate.
7 So if he -- you reviewed the
8 Madigan deposition testimony, correct?
9 A. Yes.
10 Q. So if he clarified his
11 definition of LCEs in that testimony, is
12 it your testimony that you would think
13 that's not relevant because that was not
14 cited as the basis for determining the
15 LCTs in the medical monitoring report?
16 A. Again, I don't know how he
17 clarified or if he clarified in the
18 deposition. I cannot remember in his
19 testimony whether he clarified or changed
20 the definition of an LCE.
21 And secondly, I'm not sure
22 when the medical monitoring report was
23 derived or created in respect to whether
24 or not there was a clarification made as

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1 to what an LCE is.
2 Q. That doesn't answer my
3 question.
4 You raised multiple times
5 that Madigan's deposition testimony was
6 not cited in the medical monitoring
7 report. You raised that multiple times,
8 right?
9 A. Yes, that's correct.
10 Q. I'm trying to understand why
11 that's -- why that's important to you.
12 If he didn't -- if -- so
13 here's my question.
14 If he clarified his
15 definition of LCEs in his deposition
16 testimony, is it your testimony that you
17 would think that's not relevant because
18 that was not cited as the basis for
19 determining the LCTs in the medical
20 monitoring report?
21 MR. STOY: Object to the
22 form.
23 THE WITNESS: So my response
24 is, is that I was asked to look at

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1 what evidence there is for the
2 LCTs.
3 So when I looked at the
4 medical monitoring report to see
5 how the LCTs were derived, the
6 only statement in there that was
7 relevant was that it's on the
8 basis of Dr. Madigan's and
9 Dr. Panigrahy's expert reports.
10 I do not know when the
11 medical monitoring plan was
12 devised, if it was devised after,
13 and I don't even know if Dr.
14 Madigan changed his definition of
15 LCE in his -- because I'm
16 surprised that it's not changed in
17 the actual expert -- expert
18 report.
19 So I just don't know the
20 timing of that. So again, that's
21 why I went off of what was cited
22 as the basis for the LCT, which
23 was the actual expert report.
24 BY MR. NIGH:

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1 Q. So you didn't consider
2 Dr. Madigan's testimony at all when
3 look -- deposition testimony at all when
4 looking to see what the definition of LCE
5 is in his expert report?
6 A. You know, not that I can
7 remember. I went off of what was cited
8 as the basis for coming up with the LCTs
9 within the medical monitoring report,
10 because I was told to look for evidence
11 for the basis of that.
12 The only evidence given was
13 that this was based upon his expert
14 report, and it did not say that it was
15 based upon that and his testimony.
16 Q. Okay. I want to draw your
17 attention to Page 10 of your report.
18 The very last sentence you
19 put, "It cannot be assumed that studies
20 relating to NDMA can be used to assess
21 hazard or risk with respect to NDEA.
22 Indeed, genotoxicity and carcinogenicity
23 vary greatly within the class of
24 impurities known as nitrosamines, with

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1 some, such as those found in cigarette
2 smoke, designated by IARC as Class I and
3 others falling in lower classifications."
4 Do you see that?
5 A. Yes.
6 Q. When you're making the
7 statement that it cannot be assumed that
8 studies related to NDMA can be used to
9 assess hazard or risk with respect to
10 NDEA, what documents are you relying upon
11 for that statement?
12 A. I am not relying on any
13 specific document.
14 Q. What expertise do you have
15 in terms of understanding the
16 similarities between NDMA and NDEA?
17 A. That is outside my level of
18 expertise. All I note is that I do know
19 that there are nitrosamines found in
20 cigarette smoke that are in a different
21 class from nitro -- from other agents in
22 that class. That's the extent of my
23 knowledge.
24 Q. Why would other agents in

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1 that class play upon your understanding
2 as to whether or not NDMA and NDEA are
3 similar?
4 A. Because they're agents
5 within that class.
6 Q. Did you look at the
7 similarities between NDMA and NDEA at
8 all?
9 MR. STOY: Object to the
10 form.
11 THE WITNESS: Similarities
12 with respect to what? Other than
13 being in the same class, that's
14 about the extent of it.
15 BY MR. NIGH:
16 Q. So the only statement that
17 you have for suggesting that ND -- you
18 cannot assume that studies relating to
19 NDMA can be used to assess hazard or risk
20 with respect to NDEA is simply because
21 they're in the same class?
22 MR. STOY: Object to the
23 form.
24 Go ahead.

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1 THE WITNESS: No. My -- my
2 point there is, is nitrosamines
3 include many different agents.
4 And we know that one is that
5 found in cigarette smoke, which is
6 designated by IARC as a Class I.
7 We know that NDMA and NDEA
8 are not classified as Class I; so,
9 therefore, you cannot just assume
10 blanketly that anything in the
11 class of nitrosamines are
12 identical and can be treated the
13 same way with respect to their
14 hazard.
15 BY MR. NIGH:
16 Q. Is it your belief that any
17 expert that's treating NDMA and/or -- or
18 NDMA and NDEA similarly, simply because
19 they are in the same class of
20 nitrosamines?
21 A. I'm sorry. Could you
22 rephrase that? I thought you were going
23 on. Sorry.
24 Q. Is it your belief that any

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1 expert is treating NDMA and NDEA
2 similarly, simply because they're in the
3 same class of nitrosamines?
4 A. I do not know.
5 Q. What is this criticism
6 referring to? I mean, who's giving
7 testimony that NDMA and NDEA are similar
8 or that the studies related to NDMA can
9 be used to assess hazard or risk with
10 respect to NDEA simply because they're in
11 the same class of nitrosamines? Who
12 gives that testimony?
13 A. So if you look at the entire
14 paragraph, that wasn't my intent.
15 My intent is that there is
16 only a single study on NDEA. And
17 therefore, one cannot make any sort of
18 statement of causality on the basis of
19 one study.
20 And the only other
21 implication might be that one would say,
22 well, we have all these studies on NDMA
23 where we have shown -- or have observed
24 some associations across studies;

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1 therefore, the same would hold for NDEA.
2 That was my point, that one
3 cannot do that.
4 Q. And you're saying --
5 A. There was one study on NDEA.
6 Q. And the only criticism that
7 you can come up with as to why you can't
8 look at those similarities is because
9 NDMA and NDEA are in the same class, and
10 simply being in the same class, you can't
11 look at similarities between those
12 because they're in the same class?
13 MR. STOY: Object to the
14 form.
15 THE WITNESS: Again, I'm
16 saying that with respect to the
17 associations, and if one is
18 looking at a causality-type
19 question, one cannot infer from
20 the multiple NDMA studies that one
21 would see similar -- similar
22 results if there were more than
23 one NDEA, just because they're in
24 the same class.

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1 BY MR. NIGH:
2 Q. Okay. Well, I'm going to --
3 other than just because they're in the
4 same class, I'm going to ask you, with
5 respect to the associations, and if one
6 is looking at a causality-type question,
7 one can infer from the multiple NDMA
8 studies that one would see similar
9 results if there were more than one NDEA
10 study, correct?
11 A. No, I disagree with that.
12 That was my point.
13 Q. But the only thing that
14 you're disagreeing with is because they
15 are in the same class.
16 Are there other reasons that
17 you might be able to infer studies on one
18 carcinogen that's very similar to another
19 carcinogen, other than it being in the
20 same class?
21 MR. STOY: Objection to the
22 form.
23 Also objection to the extent
24 that it's beyond the scope.

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1 THE WITNESS: Yeah, this is
2 beyond the scope of my expertise.
3 All I'm pointing out is I
4 know -- and I know from other
5 agents in other classes of drugs
6 that get tested in cancer, that
7 one, just because they're in the
8 same class, one cannot treat one
9 agent as acting the same as
10 another agent until there is
11 evidence to support that.
12 And I -- there may be
13 evidence to support that, but I
14 just said you need -- I mean, you
15 just can't assume it. That's all
16 I said.
17 BY MR. NIGH:
18 Q. What do you believe that the
19 evidence is to support it? Have you
20 looked for it or looked at it in any way?
21 MR. STOY: Objection.
22 Beyond the scope.
23 THE WITNESS: It's just
24 beyond the -- because, again, that

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1 is beyond my scope, because I was
2 not asked to look at the
3 similarities or dissimilarities.
4 All I'm saying is that there
5 is only one study done in NDEA,
6 and one cannot infer from what one
7 might infer from the multiple
8 studies in NDMA, that the same
9 would hold for NDEA just because
10 they're in the same class. That's
11 what I stated.
12 BY MR. NIGH:
13 Q. Are you aware that there are
14 entire sections dedicated to multiple of
15 plaintiffs' expert reports that are
16 dedicated to showing the similarities
17 between NDMA and NDEA? Are you aware of
18 that at all?
19 MR. STOY: Object to the
20 form.
21 THE WITNESS: I am not aware
22 of this. And again, this is
23 beyond my scope.
24 All I observed is you just

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1 can't make that inference from
2 what you found in NDMA to what
3 might happen in NDEA, just because
4 they're in the same class.
5 And it's good that there are
6 other experts that can weigh in on
7 that.
8 BY MR. NIGH:
9 Q. So since you are unaware
10 that there are entire sections dedicated
11 in multiple plaintiffs' expert reports to
12 showing the similarities between NDMA and
13 NDEA, you did not look at those
14 underlying data at all or those
15 underlying studies demonstrating those
16 similarities, correct?
17 MR. STOY: Objection.
18 Scope.
19 THE WITNESS: That's beyond
20 the scope of what I was asked to
21 do. And I did not look at those.
22 BY MR. NIGH:
23 Q. You next state, "Even
24 assuming studies concerning NDMA have

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1 some bearing on the risk associated with
2 NDEA, given the variability in the
3 reported NDMA LCE values in the dietary
4 studies found to be statistically
5 significant, it is likely that there
6 would be similar variability in the NDEA
7 levels, had more studies measured NDEA."
8 Do you see that?
9 A. Yes, I do.
10 Q. So you believe that if
11 another study were to come out and look
12 at increased risk of various types of
13 cancers versus the NDEA that they're
14 getting in their diet, that it would be
15 likely there would be similar variability
16 in the NDEA levels, had more studies
17 measured NDEA; is that accurate?
18 A. I believe so. What I was
19 saying there is that the NDMA studies
20 have a lot of variability. And that
21 variability is due to the fact that
22 they're observational studies and there's
23 all sorts of confounding, which makes the
24 values very variable.

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1 And the NDEA study that was
2 done was also an observational dietary
3 study. And if similar studies of the
4 same design came out, it's very likely,
5 just due to that residual confounding in
6 the study design of the observational
7 nature, that there would be similar
8 variability in the NDEA observed
9 associations.
10 It has to do with study
11 design.
12 Q. I want to draw your
13 attention to Page 14 in the expert
14 report.
15 And here you put at the
16 bottom of the page, "To illustrate how
17 calculations were performed, I step
18 through it for ZHP API and gastric
19 cancer."
20 And then you give two steps.
21 "To get the daily amount, divide
22 1,962 micrograms by 91.3 days. To get
23 the ppm, multiply the daily amount by
24 1,000 nanogram per microgram and divide

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1 by 320."
2 Do you see that?
3 A. Yes.
4 Q. Did you perform any other
5 steps for that calculation?
6 A. Not for the number that's in
7 Table 3 that is the number of 21.5 and
8 then the number beneath it, which is 67.2
9 parts per million. That's how I got that
10 number.
11 Q. Now, that number, the 21.5,
12 that's coming from the gastric cancer
13 dietary study, correct?
14 A. Sorry. Say that -- it's
15 coming from the LCE computed by
16 Dr. Madigan for the gastric -- for
17 gastric.
18 MR. NIGH: Can we actually
19 blow up the footnotes right below
20 the star, the one and the two with
21 the chart.
22 BY MR. NIGH:
23 Q. You footnote it. You say
24 gastric, Footnote 1, and it says from

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1 dietary exposure studies.
2 Do you see that?
3 A. Yes.
4 Q. So as you were --
5 A. And then there's an
6 asterisk -- sorry. Go ahead.
7 Q. So as you were looking at
8 the --
9 MR. NIGH: Well, keep that
10 up there, please.
11 BY MR. NIGH:
12 Q. As you were looking at
13 these, you would see that, first off, the
14 gastric LCE is coming from the dietary
15 exposure studies, correct?
16 A. From Dr. Madigan's
17 calculation of the LCE based upon the
18 dietary gastric studies.
19 Q. Okay. And so that would be
20 true for gastric, lung, esophageal and
21 rectal, correct?
22 A. Yes.
23 Q. And then for all, you're
24 getting that from Hidajat, correct?

<p>Page 190</p> <p>1 A. From the occupational 2 exposure studies, yes. And also the 3 LCE -- sorry, the LCE as computed by 4 Dr. Madigan based upon the occupational 5 study. 6 Q. So when you see gastric, 7 lung, esophageal, and rectal, those would 8 all be from dietary studies, correct? 9 A. They're the LCEs computed 10 from dietary studies, correct, as 11 computed by Dr. Madigan. 12 Q. Now, you also looked at some 13 of those underlying dietary studies, 14 correct? 15 A. I looked at them, yes. 16 Q. Did you recognize that 17 what's occurring in the dietary study is 18 you're measuring, first, people's NDMA in 19 the highest quartile, versus NDMA in the 20 lower quartile -- the lowest quartile and 21 seeing whether or not there are increased 22 risk of cancer as there are increased 23 consumptions of NDMA? 24 MR. STOY: Object to the</p> <p>Page 191</p> <p>1 form. 2 THE WITNESS: There's a lot 3 of studies there. And I cannot 4 say with any sort of certainty 5 that the studies all use the same 6 methodology. 7 So, you know, in some cases 8 that may be true. But I'd have to 9 look again at each of the studies 10 to see sort of exactly what they 11 were reporting. 12 BY MR. NIGH: 13 Q. So as you sit here today, 14 you're not sure as to whether or not 15 those studies are measuring the highest 16 group versus the lowest group or the 17 second highest group versus the lowest 18 group or the third highest group versus 19 the lowest group? 20 MR. STOY: Form objection. 21 THE WITNESS: That is 22 correct, because it doesn't matter 23 for this table, because I took the 24 LCE as computed from Dr. -- by</p>	<p>Page 192</p> <p>1 Dr. Madigan, who stated in his 2 general definition, he took the 3 lower bound of the highest group, 4 multiplied by whatever the median 5 age was, and so forth, to come up 6 with the 1,962. 7 All I'm noting there is they 8 were based on dietary studies, 9 because -- that's it. 10 So I did not go in and look 11 at each sort of gastric and see 12 exactly what they were comparing. 13 Dr. Madigan had done that. 14 BY MR. NIGH: 15 Q. I understand. But each of 16 the dietary studies, they're measuring 17 higher amounts of -- people with higher 18 amounts of NDMA compared to people with 19 lower amounts of NDMA in the diet, 20 correct? 21 A. Again, I'd have to look at 22 each study to confirm that that is the 23 case. 24 Off the top of my head, I</p> <p>Page 193</p> <p>1 just can't tell you what methodology was 2 used in each of the studies. 3 Q. At any point in your 4 calculations, did you ever consider the 5 background NDMA for the lowest quartile 6 amount of NDMA that people would be 7 getting in their diets? 8 A. I used the LCE as computed 9 by Dr. Madigan. And if he did not 10 consider that or if that was not 11 considered in the studies upon which he 12 based his LCE, then the answer would be 13 no. It's whatever was considered in 14 those studies. 15 Q. Now, you're saying -- 16 A. And I did not do -- sorry. 17 Go ahead. 18 Q. You've given me an if. If 19 it's not considered in those studies, 20 then the answer would be no. 21 My question is not an if, 22 then. 23 My question is, at any point 24 in your calculations did you ever</p>
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1 consider the background NDMA for the low
2 quartile amount of people -- or the low
3 quartile amount of NDMA that people would
4 be getting in their diet?
5 MR. STOY: Objection. Asked
6 and answered.
7 THE WITNESS: So I'm not
8 sure why I would do that. Because
9 again, for the LCTs, I was asked
10 to determine if there was evidence
11 to support the proposed LCTs in
12 the medical monitoring report.
13 And the only evidence that
14 was cited in that report for the
15 basis of those were referring to
16 the expert reports of Dr. Madigan
17 and Panigrahy.
18 So I took what Dr. Madigan
19 did, as you see there, his LCEs.
20 And again, as I stated, if
21 he did not consider the
22 background, I certainly did not,
23 because that would have gone above
24 and beyond what I was asked to do.

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1 BY MR. NIGH:
2 Q. Did you see that this is
3 explicitly mentioned in Dr. Panigrahy's
4 expert report, the same issue that I'm
5 discussing with you right now, that
6 people will have a background amount of
7 NDMA, and that this needs to be -- in
8 their diet, and that this needs to be
9 considered, as to whether or not people
10 are reaching LCEs or lifetime cumulative
11 exposures?
12 MR. STOY: Form objection.
13 THE WITNESS: I do recall
14 that he mentioned background
15 levels.
16 But in his LCE calculations,
17 he also did not provide any sort
18 of how -- he did not incorporate
19 that in his calculation as well.
20 BY MR. NIGH:
21 Q. So because he didn't
22 actually spell out the amount of NDMA
23 that would be considered for background
24 amount of NDMA, you didn't include that

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1 in your calculations as you were trying
2 to arrive to how do we reach these
3 thresholds?
4 MR. STOY: Objection.
5 Misstates her testimony.
6 THE WITNESS: So again, let
7 me go through.
8 So again, I was asked if
9 there is evidence for the basis of
10 the LCTs that are stated in the
11 medical monitoring plan.
12 And the plan says that the
13 basis for the LCTs are what is
14 reported in Dr. Panigrahy's and
15 Dr. Madigan's reports.
16 In those reports, I do
17 not -- I just use the numbers that
18 they used. So I was not -- I was
19 not developing the LCTs.
20 And therefore, I don't think
21 it would be upon me to account for
22 any background exposure levels
23 because, again, that was not
24 accounted for in the expert

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1 reports.
2 BY MR. NIGH:
3 Q. So to be clear, in all your
4 calculations that you did, you never
5 included background amount of NDMA or
6 NDEA in your calculations whatsoever,
7 correct?
8 A. Again, that is correct,
9 because in the expert reports, which was
10 the basis for the stated LCT levels in
11 the medical monitoring report, they did
12 not correct for that background
13 information.
14 So I would have been going
15 beyond what was in those expert reports
16 and adding my own to come up with the
17 LCTs, which were not my LCTs. I was not
18 asked to compute an LCT, a new one or
19 derive one.
20 Q. So even though Panigrahy
21 mentions that the LCE that he has
22 calculated also doesn't take into account
23 the threshold exposure to NDMA that a
24 valsartan patient has because of diet,

<p>Page 198</p> <p>1 you also would not have included that in 2 your calculation?</p> <p>3 A. Again, I was not asked to 4 come up with LCTs. I was asked to say, 5 is there evidence for the actual LCTs 6 that were proposed in the medical 7 monitoring plan. The only basis and 8 information given that I could find in 9 that plan for the basis of how those LCTs 10 were derived was a citation to the expert 11 reports of Dr. Panigrahy and Dr. Madigan.</p> <p>12 And in those expert reports, 13 I did not -- even though it may have been 14 mentioned that there may be background 15 NDMA or NDEA exposure, nowhere in those 16 reports was there a calculation done that 17 adjusted for those.</p> <p>18 I was not deriving the LCTs 19 de novo. That was not what I was asked 20 to do. So I did not incorporate 21 background -- or the background levels 22 because the experts had not done that.</p> <p>23 Q. Now, I want to see if I have 24 this accurate. Even though the experts</p>	<p>Page 200</p> <p>1 include that in his calculated LCE 2 levels.</p> <p>3 And I should also state that 4 in those expert reports, nowhere is there 5 a calculation of an LCT.</p> <p>6 So there -- it's just not 7 transparent as to how those LCTs were 8 calculated.</p> <p>9 So I don't think it's upon 10 me to come up with a new definition of 11 LCT that goes beyond what the experts 12 provided, which was just LCEs.</p> <p>13 Q. Did you consider 14 Dr. Madigan's testimony at all when he 15 mentioned that you would also have to 16 consider the background amount of NDMA 17 that people were getting in their diet 18 when looking at whether or not people are 19 reaching LCEs?</p> <p>20 MR. STOY: Form objection.</p> <p>21 THE WITNESS: So this goes 22 back to the similar response as 23 before, that, again, all I had to 24 go on was what was cited in the</p>
<p>Page 199</p> <p>1 specifically state how much NDMA -- or 2 even though -- sorry, strike that.</p> <p>3 I want to see if I have this 4 accurate. Even though Dr. Panigrahy 5 specifically states how much NDMA people 6 would have as a background amount, and 7 his LCEs also demonstrate for what age he 8 would have calculated, you didn't do that 9 calculation yourself in trying to see how 10 these LCTs were calculated because you 11 didn't see that specific calculation in 12 Dr. Panigrahy's report?</p> <p>13 MR. STOY: Objection. Asked 14 and answered at least ten times.</p> <p>15 You can answer it again.</p> <p>16 MR. NIGH: It's actually 17 not.</p> <p>18 THE WITNESS: That is --</p> <p>19 BY MR. NIGH:</p> <p>20 Q. So you can answer.</p> <p>21 A. That is correct. That is 22 correct. Dr. Panigrahy notes that there 23 would be some background NDEA -- NDMA 24 and/or NDEA exposure. But he did not</p>	<p>Page 201</p> <p>1 medical monitoring plan for how 2 the LCTs were derived because it 3 wasn't transparently stated in 4 there, like, here's the formula, 5 this is what we did, here's the 6 evidence, other than citing the 7 expert reports.</p> <p>8 So I went to the expert 9 reports to try to figure out how 10 to -- you know, if it was clear 11 from there, in an easy transparent 12 way of coming up with those LCT 13 levels.</p> <p>14 So I don't know if 15 Dr. Madigan in his expert report 16 even mentioned background NDMA or 17 NDEA exposures with respect to his 18 LCEs.</p> <p>19 MR. NIGH: I think now is a 20 good time to take a lunch break.</p> <p>21 MR. STOY: Okay, great.</p> <p>22 THE VIDEOGRAPHER: Off the 23 record. 12:59.</p> <p>24 - - -</p>

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1 (Whereupon a luncheon recess
2 was taken.)
3 - - -
4 THE VIDEOGRAPHER: We are
5 back on the record at 1:44 p.m.
6 - - -
7 EXAMINATION
8 - - -
9 BY MR. NIGH:
10 Q. Doctor, I'm looking at Page
11 15 of your expert report. I'm going to
12 ask you some questions here.
13 A. Okay.
14 Q. So specifically, you give
15 the statement, "Comparing these values to
16 the level of impurity cited in
17 Dr. Panigrahy's report, there is no match
18 except for ZHP API, but only for gastric
19 cancer if we take the average of the
20 midpoints for ZHP, which is approximately
21 66.4 ppm."
22 How do you -- how did you
23 figure that the midpoint -- if you take
24 the average of the midpoints for ZHP that

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1 you would reach those levels for gastric
2 cancer?
3 A. So, you know, I was trying
4 to see if I could come up with the
5 numbers in any way. So I was trying
6 various other sort of combinations that
7 were suggested in the past as to whether
8 I looked at sort of midpoints or averages
9 or things like that.
10 So that was just the thing
11 that came sort of closest to the number
12 in the table above.
13 Q. So you looked at the levels
14 reported in Dr. Panigrahy's report to
15 make this statement?
16 A. At this time, I'm not sure
17 if I did the midpoints from that report
18 or some other report. And I see that I
19 do not cite it there.
20 But it looks like I took it
21 from his report.
22 Q. Did you also look at the
23 underlying document to confirm that that
24 document indeed showed those ranges for

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1 ZHP API?
2 A. I'm sorry. Could you
3 specify which document?
4 Q. Whichever document that
5 Dr. Panigrahy was citing for that --
6 those values?
7 A. I don't remember at this
8 point if I actually looked at the
9 document from where he took those values
10 or not.
11 Q. On the table above, it shows
12 cancers, and it shows gastric cancer,
13 lung, esophageal, rectal, and all.
14 Do you see that?
15 A. In Table 3?
16 Q. Table 3, correct.
17 A. Yep. Yes.
18 Q. And in fact, actually the
19 two, that refers to -- under all, that
20 refers to occupational exposure studies,
21 correct?
22 A. That is correct.
23 Q. Now, when you put the words
24 "all" there in this chart, are you

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1 referring to all the cancers other than
2 gastric, lung, esophageal, and rectal?
3 A. I'd have to look at the
4 occupational exposure study or
5 Dr. Madigan's report.
6 So I got that from Number
7 34 -- or Paragraph 34 in Dr. Madigan's
8 report, per Hidajat. I'm not sure if I'm
9 pronouncing the name right.
10 Cumulative exposure greater
11 than 75 -- that number, 7,514
12 statistically significant increases one's
13 risk of developing the following cancers.
14 So what I meant by all are
15 bladder, lung, stomach, multiple myeloma,
16 esophageal, prostate. Even though it
17 says prostate twice, I presume he meant
18 one of those times to be pancreas.
19 Q. Okay. And so when you're
20 looking at all, you're referring to each
21 of those individual cancers increased
22 risk seen in the Hidajat study, correct?
23 A. Yes. That's my
24 understanding of what Dr. Madigan is

<p>Page 206</p> <p>1 saying there, that at that level, each of 2 those individual cancers had an 3 association with the corresponding cancer 4 at that level. 5 Q. In your -- in terms of 6 looking at whether or not there is an 7 increased risk of all cancer, did you see 8 any studies that actually looked -- 9 lumped all cancers together to see if 10 there was an increase in the risk of all 11 cancer, you know, for people taking NDMA 12 versus -- or for people having higher 13 amounts of NDMA versus people having 14 exposure to lower amounts of NDMA? 15 A. Off of the top of my head, I 16 cannot say with certainty whether any of 17 those manuscripts just did a calculation 18 for any type of cancer and then broke it 19 into the individual cancers, but that's 20 not what I meant by "all" there. 21 MR. NIGH: All right. I 22 don't have any further questions. 23 Thank you, Doctor. 24 MR. STOY: Okay. Daniel,</p> <p>Page 207</p> <p>1 let's take five minutes and we'll 2 come back on. 3 MR. NIGH: Sounds good. 4 THE VIDEOGRAPHER: Off the 5 record. 1:52. 6 (Short break.) 7 THE VIDEOGRAPHER: We are 8 back on the record at 1:57 p.m. 9 MR. STOY: Okay. 10 Dr. Ballman, I don't have any 11 questions for you. 12 We will read and sign. 13 And I believe that concludes 14 the deposition. 15 MR. NIGH: Thank you for 16 your time, Dr. Ballman. 17 Appreciate it. 18 THE WITNESS: Nice to meet 19 you, Mr. Nigh. 20 MR. NIGH: You too. 21 THE VIDEOGRAPHER: That 22 concludes today's deposition. The 23 time is 1:57 p.m. 24</p>	<p>Page 208</p> <p>1 ***** 2 (Excused.) 3 (Deposition concluded at 4 approximately 1:59 p.m.) 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24</p> <p>Page 209</p> <p>1 2 CERTIFICATE 3 4 5 I HEREBY CERTIFY that the 6 witness was duly sworn by me and that the 7 deposition is a true record of the 8 testimony given by the witness. 9 10 It was requested before 11 completion of the deposition that the 12 witness, KARLA V. BALLMAN, Ph.D., have 13 the opportunity to read and sign the 14 deposition transcript. 15 16 MICHELLE L. GRAY, 17 A Registered Professional 18 Reporter, Certified Shorthand 19 Reporter, Certified Realtime 20 Reporter and Notary Public 21 Dated: February 24, 2022 22 23 (The foregoing certification 24 of this transcript does not apply to any reproduction of the same by any means, unless under the direct control and/or supervision of the certifying reporter.)</p>
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INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it.

You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

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ACKNOWLEDGMENT OF DEPONENT

I, _____, do hereby certify that I have read the foregoing pages, 1 - 213, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

KARLA V. BALLMAN, Ph.D. DATE _____

Subscribed and sworn to before me this _____ day of _____, 20____.

My commission expires: _____

Notary Public

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LAWYER'S NOTES

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Exhibit 206

REDACTED

1 UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY
2
3 IN RE: VALSARTAN,)
LOSARTAN, AND IRBESARTAN)
4 PRODUCTS LIABILITY)
LITIGATION)
5 _____) MDL NO. 2875
HON. ROBERT B. KUGLER
6 THIS DOCUMENT RELATES TO)
ALL CASES)
7)
8
9
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11

9 CONFIDENTIAL INFORMATION - SUBJECT TO
10 PROTECTIVE ORDER
11

12 VIDEOTAPED DEPOSITION OF:
13 MICHAEL BOTTORFF, PHARM.D.
14 Taken on behalf of the Plaintiffs
15 March 25, 2022
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25

<p style="text-align: right;">Page 2</p> <p>1 REMOTE APPEARANCES: 2 For the Plaintiffs: 3 C. BRETT VAUGHN, ESQ. Hollis Law Firm 4 8101 College Boulevard Suite 260 5 Overland Park, Kansas 66210 6 For the Defendants, Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals 7 SA, Inc., Actavis LLC, and Actavis Pharma, Inc.: STEPHEN T. FOWLER, ESQ. 8 Greenberg Traurig, LLP 2101 L Street, N.W. Suite 1000 9 Washington, D.C. 20037 202.331.3100 10 Fowlerst@gtlaw.com 11 Also Present Remotely: 12 Alice Springer 13 Bailey Hughes Christine Gannon 14 Daniela Tenjidor Geoffrey Coan 15 George Williamson Gerond Lawrence 16 Iris Simpson Ken Dzikowski 17 Marlene J. Goldenberg Melissa Catello 18 Melisha Valenzuela William Murtha 19 Phillip Todd - Videographer 20 21 22 23 24 25</p>	<p style="text-align: right;">Page 4</p> <p>1 Exhibit 12 Document Torrent-MDL 145 25 2875-00259489 2 Exhibit 13 Document 149 21 3 RO-MDL-2875-0061940 4 Exhibit 14 Document 158 2 RO-MDL-2875-0004639 5 Exhibit 15 RO-MDL- 2875-0026534 165 7 6 Exhibit 16 Document 168 21 7 RO-MDL-2875-0080263 8 Exhibit 17 Document 175 1 9 Mylan-MDL-2875-00001448 Exhibit 18 Document Mylan-MDL 175 5 10 2875-00031265 11 Exhibit 19 "PRACS Cetero Bankruptcy" 176 2 Article 12 Exhibit 20 FDA letter to Cetero 177 5 13 Research 14 Exhibit 21 "Teva and Cipla will have 182 21 ANDAs Withdrawn" Article 15 Exhibit 22 Document Teva-MDL- 185 14 16 2875-00003105 17 Exhibit 23 Document Teva-MDL- 187 13 2875-00003194 18 Exhibit 24 Document Teva-MDL- 189 8 19 2875-00268983 20 Exhibit 25 Document Teva- MDL 191 18 2875-00102393 21 Exhibit 26 Document ZHP 01453143 197 23 22 Exhibit 27 Document Princeton 00179194 199 19 23 Exhibit 28 Document Princeton 00134669 202 16 24 Exhibit 29 Document Princeton 00369303 207 14 25</p>
<p style="text-align: right;">Page 3</p> <p>1 I N D E X 2 3 Page/Line 4 THE WITNESS: MICHAEL BOTTORFF, PHARM.D. 8 9 EXAMINATION BY MR. VAUGHN 241 25 5 EXAMINATION BY MR. FOWLER EXAMINATION BY MR. VAUGHN 6 7 8 INDEX OF EXHIBITS 9 Exhibits Description Page/Line 10 Exhibit 1 Class Action Expert Report 10 11 11 Exhibit 2 General Causation Report 10 21 12 Exhibit 3 Invoices 33 25 13 Exhibit 4 2011 FDA Guidance for 95 3 Submission of Summary 14 Bioequivalence Data for ANDAs 15 Exhibit 5 FDA's 2021 Draft Guidance 97 3 16 Exhibit 6 Notice of Deposition 107 11 17 Exhibit 7 Document Teva-MDL 112 20 18 2875-00808468 19 Exhibit 8 Document Hetero_USA 124 14 000029545 20 Exhibit 9 Document Hetero_USA 129 18 21 000005016 22 Exhibit 10 Document Torrent-MDL 142 25 287500003049 23 Exhibit 11 Document Torrent-MDL 145 21 24 2875-00003054 25</p>	<p style="text-align: right;">Page 5</p> <p>1 Exhibit 30 Document Princeton 00153602 210 13 2 Exhibit 31 EMA Press Release regarding 217 20 GVK Biosciences 3 Exhibit 32 Document ZHP 00378002 220 17 4 Exhibit 33 Document Teva-MDL 226 11 5 2875-00117673 6 Exhibit 34 Document Bottorff 0001 230 23 7 Exhibit 35 Defendants' Responses and 242 7 Objections to Plaintiffs' 8 Notice of Videotaped Oral Deposition Michael 9 Bottorff, Pharm.D 10 Exhibit 36 Curriculum Vitae 242 16 11 Exhibit 37 21 CFR 314.3 Definitions 244 14 12 Exhibit 38 Materials Considered List 260 9 13 Exhibit 39 Flash Drive of Dr. 260 23 Bottorff's Materials 14 Considered (late-filed) 15 16 17 18 19 20 21 22 23 24 25</p>

<p>Page 6</p> <p>1 The videotaped deposition of</p> <p>2 MICHAEL BOTTORFF, PHARM.D., was taken by</p> <p>3 counsel for the Plaintiffs, on March 25,</p> <p>4 2022, commencing at 9:39 a.m. Eastern,</p> <p>5 via remote proceedings, for all purposes</p> <p>6 under the Tennessee Rules of Civil</p> <p>7 Procedure.</p> <p>8 The formalities as to notice,</p> <p>9 caption, certificate, et cetera, are not</p> <p>10 waived. All objections, except as to</p> <p>11 the form of the questions, are reserved</p> <p>12 to the hearing.</p> <p>13 It is agreed that Carissa L.</p> <p>14 Boone, being a Notary Public and Court</p> <p>15 Reporter, may swear the witness, and</p> <p>16 that the reading and signing of the</p> <p>17 completed deposition by the witness are</p> <p>18 not waived.</p> <p>19</p> <p>20</p> <p>21 * * *</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>Page 8</p> <p>1 MICHAEL BOTTORFF, PHARM.D.</p> <p>2 having been first duly sworn, was examined and</p> <p>3 testified as follows:</p> <p>4 THE VIDEOGRAPHER: I'm sorry, I</p> <p>5 did not hear anything from the witness.</p> <p>6 I'm sorry, I did not hear</p> <p>7 anything from the witness.</p> <p>8 THE WITNESS: I said "I do."</p> <p>9 EXAMINATION</p> <p>10 BY MR. VAUGHN:</p> <p>11 Q. All right, Dr. Bottorff. My name</p> <p>12 is Brett Vaughn. You remember I took your</p> <p>13 deposition about six months ago in the general</p> <p>14 causation stage of the personal injury cases,</p> <p>15 correct?</p> <p>16 A. I do remember you, yes.</p> <p>17 Q. And you've now submitted an</p> <p>18 expert report for the class action side of this</p> <p>19 litigation?</p> <p>20 A. Correct.</p> <p>21 Q. And did you use your general</p> <p>22 causation expert report as the base of your class</p> <p>23 action expert report?</p> <p>24 A. There was some overlap in what</p> <p>25 seemed to be some of the issues between the class</p>
<p>Page 7</p> <p>1 THE VIDEOGRAPHER: Good morning.</p> <p>2 We are now on the record. My name is</p> <p>3 Phillip Todd. I am the videographer for</p> <p>4 Golkow Litigation Services.</p> <p>5 Today's date is March 25th, 2022,</p> <p>6 and the time is 9:39 a.m. Eastern.</p> <p>7 This remote video deposition is</p> <p>8 being held in the matter of Valsartan,</p> <p>9 Losartan and Irbesartan Products</p> <p>10 Liability Litigation in the United</p> <p>11 States District Court, District of New</p> <p>12 Jersey.</p> <p>13 The deponent is Dr. Michael</p> <p>14 Bottorff.</p> <p>15 All parties in this deposition</p> <p>16 are appearing remotely and have agreed</p> <p>17 to the witness being sworn in remotely.</p> <p>18 Due to the nature of remote</p> <p>19 reporting, please pause briefly before</p> <p>20 speaking to ensure all parties are heard</p> <p>21 completely.</p> <p>22 Counsel will be noted on the</p> <p>23 stenographic record.</p> <p>24 The court reporter, Carissa</p> <p>25 Boone, will now swear in the witness.</p>	<p>Page 9</p> <p>1 action and the general causation, so there were</p> <p>2 some elements that are similar in both.</p> <p>3 Q. And is this meant to supercede</p> <p>4 your general causation expert report?</p> <p>5 MR. FOWLER: Objection, form.</p> <p>6 THE WITNESS: Not to supercede.</p> <p>7 As -- as part of my academic career,</p> <p>8 whenever there's a -- a literature</p> <p>9 search and evaluation, a -- a process</p> <p>10 that you go through, you review and add</p> <p>11 information to what you already know.</p> <p>12 So it's not meant to replace previous</p> <p>13 information, if that's what the question</p> <p>14 was.</p> <p>15 BY MR. VAUGHN:</p> <p>16 Q. And so what content did you add</p> <p>17 to this expert report?</p> <p>18 A. I think the biggest addition is</p> <p>19 the bioequivalence description assessment and</p> <p>20 analysis and a section on the process of</p> <p>21 pharmacokinetic accumulation. And then a -- a</p> <p>22 third area was a -- a section where I comment on</p> <p>23 the -- the need for medical monitoring.</p> <p>24 Q. And you said that the purpose of</p> <p>25 this was not to replace previous information.</p>

<p style="text-align: right;">Page 10</p> <p>1 Were there changes actually made, though, to your 2 general causation opinions in here? 3 MR. FOWLER: Objection, form. 4 THE WITNESS: I don't recall 5 making any changes to my previous report 6 in this report. 7 MR. VAUGHN: Melisha, can we go 8 ahead and pull up the class action 9 expert report he submitted? 10 And that will be Exhibit 1. 11 (Exhibit 1 was marked.) 12 BY MR. VAUGHN: 13 Q. And, Mr. Bottorff, is this 14 your -- the expert report you submitted for the 15 class action in this litigation? 16 A. Yes, it is. 17 MR. VAUGHN: And, Melisha, can we 18 split-screen that with his general 19 causation report? 20 And let's mark that as Exhibit 2. 21 (Exhibit 2 was marked.) 22 BY MR. VAUGHN: 23 Q. Now, turning -- 24 MR. VAUGHN: On the class action 25 expert report, can we please go to page</p>	<p style="text-align: right;">Page 12</p> <p>1 highlighting in blue. Or now yellow. 2 BY MR. VAUGHN: 3 Q. Do you have your class action 4 expert report with you? 5 A. Yes. 6 Q. Can you find anywhere in your 7 class action expert report where -- where it still 8 discusses ZHP's internal nitrosamine testing on 9 their API? 10 A. Yeah, I don't -- I don't see it. 11 Q. Are you the one that removed that 12 from your expert report? 13 A. I probably was, since I wrote 14 this myself. 15 Q. Why did you remove that from your 16 expert report? 17 MR. FOWLER: Objection to form, 18 "remove." 19 Go ahead, Doctor. 20 THE WITNESS: I can't tell you 21 right now why I did not include the same 22 wording. The -- the following 23 information, which is the -- the FDA 24 values, I believe they are identical. 25 BY MR. VAUGHN:</p>
<p style="text-align: right;">Page 11</p> <p>1 7, Melisha? And on the general 2 causation report, can we go to page 6. 3 BY MR. VAUGHN: 4 Q. Okay. So on the right-hand side, 5 you see on your general causation report, 6 you -- line 114, that entire paragraph, you note: 7 "When ZHP became aware of the nitrosamine 8 impurities, ZHP tested certain of its inactive 9 ingredient -- active pharmaceutical ingredient 10 batches and determined that the levels of NDMA 11 range from 3.4 parts per million to 120 parts per 12 million"? 13 Do you see that, Dr. Bottorff? 14 A. Yes. Is that what you 15 highlighted in yellow? 16 Q. Correct. 17 And then it -- looking at your 18 class action expert report page 7, line 140, you 19 see that it's now been changed to the FDA testing 20 and any mention of ZHP's testing has been dropped 21 from your expert report? 22 MR. FOWLER: Objection to form, 23 "changed." 24 Go ahead, Doctor. 25 THE WITNESS: I see where you're</p>	<p style="text-align: right;">Page 13</p> <p>1 Q. But ZHP's values are higher than 2 the FDA's values, aren't they? 3 MR. FOWLER: Objection. 4 THE WITNESS: If I went back and 5 calculated. (Technical interference) 6 probably do that. But I think -- 7 BY MR. VAUGHN: 8 Q. But -- 9 A. -- they are higher. 10 MR. VAUGHN: All right. Melisha, 11 can we go to page 22 on the class action 12 report now? And let's compare that to 13 page 21 of the general causation report. 14 All right. And I'm looking at 15 line 364 where it says: "Presence of 16 trace amounts of NDMA/NDEA on the 17 general causation report," Melisha. The 18 one on the right. Line 364. Yeah. 19 BY MR. VAUGHN: 20 Q. And then -- you see that, Doctor, 21 line 364, where you note the -- the amounts being 22 trace amounts? 23 A. Yes. 24 Q. Okay. And can we compare that, 25 then, to your class action expert report on page</p>

<p style="text-align: right;">Page 14</p> <p>1 22, line 374? It now says: "Presence of NDMA and 2 NDEA," the words "trace amounts" have been dropped 3 from your expert report, correct? 4 A. They're not there. 5 Q. Are you the one that removed 6 those words? 7 A. I wrote this, so I must have. 8 Q. Why did you remove those words 9 from your expert report? 10 A. I have no particular reason. 11 MR. VAUGHN: All right. Melisha, 12 let's go to page 45 of this class action 13 expert report. And let's compare that 14 to page 25 of his general causation 15 expert report. 16 BY MR. VAUGHN: 17 Q. In the general causation expert 18 report on that line 439, the sentence that reads: 19 "The concern over the detection of these 20 impurities is that the international agency for 21 research on cancer, IARC, has categorized 22 nitrosamines as a probable human carcinogen based 23 on annual studies primarily involving rats." 24 Do you see that in your general 25 causation report, Mr. Bottorff?</p>	<p style="text-align: right;">Page 16</p> <p>1 MR. VAUGHN: Let's go to page 47 2 of his class action report, and let's 3 compare that to page 27 of his general 4 causation expert report. 5 BY MR. VAUGHN: 6 Q. And on your general causation 7 expert report, I'm looking at the lines 473 and 8 474. So it ends with: "The carcinogens produced" 9 at 473. 10 Do you see where I'm looking at, 11 Mr. Bottorff? 12 A. Yes. 13 Q. And so now if you look at the 14 class action expert report Line No. 749, you've 15 now inserted a heading "NDE" -- "NDMA and NDEA and 16 valsartan will not reach systemic circulation." 17 Do you see that, Dr. Bottorff? 18 A. I do. 19 Q. Why was that added to your expert 20 report? 21 MR. FOWLER: Objection to form, 22 "added." 23 THE WITNESS: I guess I was 24 trying to -- doing what I would call 25 sort of format form, outline form, sort</p>
<p style="text-align: right;">Page 15</p> <p>1 A. I do. 2 Q. Okay. Now looking at your class 3 action expert report line 724, that entire 4 sentence is no longer in your expert report, is 5 it? 6 A. No. 7 Q. And did you remove that language 8 from your expert report as well? 9 A. It's not there, so it got 10 removed. But it wasn't removed for any particular 11 reason that I can give you. 12 Q. And you're the one that removed 13 that language? 14 A. I wrote this, so it would have 15 been me. 16 Q. And there's no particular reason 17 you removed the language about nitrosamines being 18 probable human carcinogens? 19 MR. FOWLER: Objection, form. 20 Other than the scope of the 21 report? 22 THE WITNESS: And so, no, 23 I -- I'm -- I'm the one, if it came out, 24 that took it out. And there was no 25 particular reason for that.</p>	<p style="text-align: right;">Page 17</p> <p>1 of identify areas in this second report 2 that I would have sections on. So it 3 was a -- working from an outline to the 4 report. 5 BY MR. VAUGHN: 6 Q. And does NDMA or NDEA reaching 7 systemic circulation have anything to do with 8 bioequivalency studies? 9 A. The presence of NDMA and NDEA in 10 valsartan, are you asking if that would have an 11 effect on valsartan's bioequivalence? 12 Q. Correct. Does NDMA or NDEA being 13 in valsartan and the NDMA or NDEA reaching 14 systemic circulation, does that have any impact on 15 valsartan bioequivalency studies? 16 MR. FOWLER: Objection: Form, 17 compound. 18 THE WITNESS: First, I'm -- I'm 19 trying to speak real loud to make sure 20 that you can hear. So if it seems like 21 I'm yelling, it's not in an -- an 22 aggressive kind of response. 23 BY MR. VAUGHN: 24 Q. I appreciate it and your -- your 25 level is actually pretty good.</p>

<p style="text-align: right;">Page 18</p> <p>1 A. Okay. I -- I just didn't want it 2 to come across as -- but I wanted to be sure I got 3 heard. 4 No, I do not believe that the 5 presence of NDMA or NDEA in valsartan has anything 6 to do with valsartan's bioequivalence. 7 Q. And it reaching systemic 8 circulation -- scratch that. 9 And NDMA or NDEA reaching 10 systemic circulation has nothing to do with the 11 bioequivalency studies for valsartan, correct? 12 MR. FOWLER: Objection: Form, 13 lack of foundation, facts not in 14 evidence. 15 THE WITNESS: Because I conclude 16 that they would not reach the systemic 17 circulation, then, again, my best answer 18 to your question is that they have no 19 effect on valsartan's bioequivalence. 20 BY MR. VAUGHN: 21 Q. The opinion that NDMA and NDEA in 22 valsartan will not reach systemic circulation is 23 in relation to your general causation opinions, 24 correct? 25 MR. FOWLER: Objection: Form,</p>	<p style="text-align: right;">Page 20</p> <p>1 almost completely, minimizing exposure to other 2 tissues and organs." 3 Do you see that in your prior 4 report, Dr. Bottorff? 5 A. I do. 6 Q. All right. And let's compare 7 that to the sentence that starts on lines 761 of 8 your class action expert report that reads: "Oral 9 doses at the levels detected in generic valsartan 10 at issue in this litigation are metabolized in the 11 liver almost completely, preventing exposure to 12 other tissues and organs." 13 Did I read that correctly, 14 Dr. Bottorff? 15 A. Yes. 16 Q. What changes did you make in that 17 sentence from your general causation expert report 18 to your class action expert report? 19 A. I don't feel that I made any 20 substantial changes at all. 21 Q. Okay. Do you see in the general 22 causation report you used the word "minimizing 23 exposure to other tissues and organs"? The word 24 "minimizing"? 25 A. Yes.</p>
<p style="text-align: right;">Page 19</p> <p>1 mischaracterizes. 2 THE WITNESS: I think it's, as I 3 said earlier, that there is some overlap 4 in some of the issues between general 5 causation and this part of the 6 litigation, as I understood it, and the 7 concept of -- of first pass metabolism 8 is one of those areas of overlap between 9 the two reports. 10 BY MR. VAUGHN: 11 Q. How does first pass metabolism of 12 NDMA or NDEA impact the bioequivalency studies of 13 valsartan? 14 A. It does not. 15 MR. VAUGHN: Melisha, let's go to 16 page 48 of his class action expert 17 report. Let's compare that to page 28 18 of his general causation expert report. 19 Looking at line 486 of his general 20 causation report where it says: 21 "Minimizing exposure to other tissues 22 and organs..." 23 BY MR. VAUGHN: 24 Q. And the full sentence reads: 25 "Smaller oral doses are metabolized in the liver</p>	<p style="text-align: right;">Page 21</p> <p>1 Q. And do you see that that's been 2 changed to the word "preventing"? It now says: 3 "...preventing exposure to other tissues and 4 organs." 5 Do you see that? 6 A. I do. 7 Q. Do you not think there's much of 8 a difference between "minimizing" and 9 "preventing"? 10 MR. FOWLER: Objection, 11 argumentative. 12 THE WITNESS: Conceptually, what 13 those two sentence [sic] were -- I think 14 mean the same thing about -- because of 15 first pass metabolism, that you minimize 16 exposure, you prevent exposure, you 17 minimize/eliminate risk, and I think 18 they're -- they're just a reflection of 19 the fact that I did not just simply cut 20 and paste from my previous report 21 into -- into this report. I -- I sat 22 down and wrote it de novo with the same 23 knowledge base and information. 24 BY MR. VAUGHN: 25 Q. And this sentence that you</p>

<p>Page 22</p> <p>1 changed has nothing to do with the bioequivalency</p> <p>2 studies, correct?</p> <p>3 A. Correct.</p> <p>4 MR. VAUGHN: Let's go to page 52</p> <p>5 of his class action expert report,</p> <p>6 Melisha. And let's compare that to page</p> <p>7 62 of his general causation expert</p> <p>8 report.</p> <p>9 BY MR. VAUGHN:</p> <p>10 Q. All right. In looking at the</p> <p>11 class action expert report, line 830, do you see</p> <p>12 where you note that: "DNA repair mechanisms in</p> <p>13 humans can be as much as ten times higher than</p> <p>14 rats"?</p> <p>15 A. Yes.</p> <p>16 Q. Okay. And looking at your</p> <p>17 general causation expert report, do you see that</p> <p>18 language anywhere?</p> <p>19 A. Not in the page that -- that you</p> <p>20 have in front of me.</p> <p>21 Q. Do -- do you have your general</p> <p>22 causation expert report?</p> <p>23 A. I can probably get a hard copy</p> <p>24 because we have a printer here, but I don't have</p> <p>25 it sitting right in front of me.</p> <p>Page 23</p> <p>1 Q. Okay. You can also download it</p> <p>2 from the exhibit share file, if you would like to.</p> <p>3 All right. Dr. Bottorff, if you</p> <p>4 could, could you review your general expert report</p> <p>5 and see if anywhere in that report you gave the</p> <p>6 opinion that DNA repair mechanisms in humans can</p> <p>7 be as much as ten times higher than rats?</p> <p>8 MR. VAUGHN: And let's go ahead</p> <p>9 and go off the record while he's</p> <p>10 reviewing this document.</p> <p>11 THE VIDEOGRAPHER: The time is</p> <p>12 now 9:59 a.m. We are off the record.</p> <p>13 (Brief recess observed.)</p> <p>14 THE VIDEOGRAPHER: 10:06 a.m.,</p> <p>15 we're back on the record.</p> <p>16 BY MR. VAUGHN:</p> <p>17 Q. All right. Dr. Bottorff, now</p> <p>18 that you've had time to review your general</p> <p>19 causation expert report, did you find anywhere</p> <p>20 within that report that you gave the opinion that</p> <p>21 DNA repair mechanisms in humans can be as much as</p> <p>22 ten times higher than rats?</p> <p>23 A. No, I -- I didn't find it.</p> <p>24 And -- and what I was looking for and what I</p> <p>25 thought I had in there -- and it may still be in</p>	<p>Page 24</p> <p>1 there; I just didn't have enough time to find</p> <p>2 it -- is I thought I made a statement somewhere in</p> <p>3 the report that said that the metabolism of -- of</p> <p>4 NDMA in the liver was occurring in the organ that</p> <p>5 had the highest capacity to metabolize it.</p> <p>6 And that -- that may be in there</p> <p>7 somewhere if I go line-by-line and try to find it.</p> <p>8 So I may not have quantified it in the original</p> <p>9 report, and I quantified it here from a statement</p> <p>10 made in -- in one of the PEG articles.</p> <p>11 Q. Does quantifying the DNA repair</p> <p>12 mechanisms in humans compared to rats have</p> <p>13 anything to do with your class action opinions?</p> <p>14 A. Yes.</p> <p>15 Q. I'm sorry? I didn't hear that</p> <p>16 answer.</p> <p>17 A. Sorry. Yes.</p> <p>18 Q. What does it have to -- what</p> <p>19 does -- scratch that.</p> <p>20 What do DNA repair mechanisms in</p> <p>21 humans have to do with your class action expert</p> <p>22 report?</p> <p>23 A. The issue of medical monitoring.</p> <p>24 Q. And how does that relate to</p> <p>25 medical monitoring?</p> <p>Page 25</p> <p>1 A. Based on first pass metabolism</p> <p>2 and limiting exposure of NDMA and NDEA to the</p> <p>3 liver, which has the best capability for DNA</p> <p>4 repair mechanisms, would mean that there's no</p> <p>5 exposure enough to downstream organs to justify</p> <p>6 medical monitoring, based on these principles of</p> <p>7 both first pass metabolism and DNA repair.</p> <p>8 Q. So would it be fair to say that</p> <p>9 the DNA repair mechanisms relate to your class</p> <p>10 action expert report because you don't believe</p> <p>11 that nitrosamines can increase the risk of cancer</p> <p>12 in humans?</p> <p>13 MR. FOWLER: Objection, form.</p> <p>14 THE WITNESS: Yes. And that's</p> <p>15 consistent with what I concluded in my</p> <p>16 original report, and it's a portion of</p> <p>17 what I continue to conclude in this</p> <p>18 expert report.</p> <p>19 BY MR. VAUGHN:</p> <p>20 Q. And so you would agree that's a</p> <p>21 general causation expert opinion, the DNA repair</p> <p>22 mechanisms in humans?</p> <p>23 MR. FOWLER: Objection: Form,</p> <p>24 mischaracterizing.</p> <p>25 THE WITNESS: I would agree that</p>
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<p style="text-align: right;">Page 26</p> <p>1 it has relevance to both the general 2 causation issue in my original report 3 and to the medical monitoring issue that 4 I addressed in this report. 5 BY MR. VAUGHN: 6 Q. And when we went off the record 7 for you to review your general causation expert 8 report and Mr. Fowler went off the screen, did he 9 discuss any part of your testimony with you? 10 A. No. None at all. 11 MR. VAUGHN: All right. Melisha, 12 can we go just to his class action 13 expert report, which is Exhibit 1. And 14 let's go to page 50 and look at line 15 802. 16 BY MR. VAUGHN: 17 Q. Doctor, in this paragraph, you're 18 discussing the half-life of NDMA, correct? 19 A. Correct. 20 Q. And in your opinion, what is the 21 half-life of NDMA in humans? 22 A. It's estimated to be about 13 23 minutes. 24 Q. And what are you basing that 25 estimation on?</p>	<p style="text-align: right;">Page 28</p> <p>1 THE WITNESS: It is as a result 2 of metabolism, and to a certain degree, 3 distribution after IV administration 4 that would result in taking 13 minutes 5 in the estimate in humans, and anywhere 6 between 4 and 26 minutes in other animal 7 species who received IV dosing, for that 8 original concentration to be cut in 9 half, and in that same amount of time, 10 for that concentration to be cut in 11 half. 12 BY MR. VAUGHN: 13 Q. So let me make sure I 14 understand -- 15 A. -- and approximately -- 16 Q. I apologize. 17 A. Sorry, go ahead. 18 Q. I'm sorry if I cut you off -- 19 MR. FOWLER: Let's not -- 20 BY MR. VAUGHN: 21 Q. -- with the delay. 22 MR. FOWLER: -- do that. Yeah. 23 BY MR. VAUGHN: 24 Q. It -- it was not intentional. 25 A. Yeah, so I'll -- I'll finish, and</p>
<p style="text-align: right;">Page 27</p> <p>1 A. I'm using the clearance values 2 from one of the Gombar papers. 3 Q. Did you find the Gombar paper to 4 be reliable? 5 MR. FOWLER: Objection, form. 6 THE WITNESS: In some respects. 7 BY MR. VAUGHN: 8 Q. What is half-life? 9 A. The time it takes for a compound 10 amount to be cut in half. 11 Q. What do you mean "cut in half"? 12 A. Drop by 50 percent. 13 Q. Is that after it's been ingested? 14 A. No. These diag- -- these numbers 15 came from the intravenous data from Gombar, which 16 is the part that I don't have any problem with at 17 all. 18 Q. But the half-life is in relation 19 to the substance being inside the body, correct? 20 A. And in this case, getting there 21 by giving it IV. 22 Q. And so that would mean after 13 23 minutes, if no metabolism is taking place of the 24 NDMA, half of it will have disappeared? 25 MR. FOWLER: Objection, form.</p>	<p style="text-align: right;">Page 29</p> <p>1 then we can take that question. 2 So literally what it amounts to 3 is whatever that original concentration is after 4 you give it intravenously, the half-life -- let's 5 take a round number of ten minutes. It would take 6 ten minutes for that concentration to be cut in 7 half. In ten more minutes, that would be cut in 8 half. And by the time you got to five of those, 9 you can't detect the drug anymore. So a general 10 pharmacology rule is five half-lives and the drug 11 is essentially completely gone. 12 Q. So did I understand you correctly 13 that if NDMA is given intravenously to a human, 14 it's going to take approximately 13 minutes for it 15 to decrease by half? 16 A. An estimate from the Gombar data 17 would predict that, if you were to give it IV. 18 Q. And do you agree with that 19 estimate in Gombar? 20 A. I think it's actually a pretty 21 good estimate. 22 Q. Would it matter how much of a 23 dose is given IV? Will that impact the half-life 24 at all? 25 A. It could.</p>

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<p>1 Q. How so?</p> <p>2 A. If -- if a smaller dose is given</p> <p>3 that is in the range of what we call linear</p> <p>4 pharmacokinetics, you'll get a -- a half-life</p> <p>5 value. And if -- if it's a process that can be</p> <p>6 saturated and you give a multiple higher dose,</p> <p>7 then you would saturate elimination and you would</p> <p>8 get a measured longer half-life.</p> <p>9 Q. And in the Gombar study where you</p> <p>10 drew this 13-minute half-life, was it saturated or</p> <p>11 not?</p> <p>12 A. Gombar used his nonsaturated IV</p> <p>13 dose to calculate and then estimate what he</p> <p>14 thought it would be in humans.</p> <p>15 Q. And so in a nonsaturated IV dose</p> <p>16 in humans, NDMA would take 13 minutes to reduce</p> <p>17 the amount in half?</p> <p>18 A. That is an estimate from the</p> <p>19 Gombar data.</p> <p>20 Q. Doctor, do you know how long it</p> <p>21 takes for the blood to do a full circulation in</p> <p>22 the human body?</p> <p>23 A. Off the top of my head, I -- I</p> <p>24 don't. I know I used to know that. And sometimes</p> <p>25 you'll see that expressed as how many cycles per</p>	<p>1 BY MR. VAUGHN:</p> <p>2 Q. If the blood can go all the way</p> <p>3 around the human body multiple times in 13</p> <p>4 minutes, the NDMA would be crossing the liver</p> <p>5 multiple times, wouldn't it?</p> <p>6 MR. FOWLER: Objection: Form,</p> <p>7 lack of foundation, facts not in</p> <p>8 evidence, incomplete hypothetical.</p> <p>9 THE WITNESS: The -- the best</p> <p>10 answer I can give you in a conceptual is</p> <p>11 that when a drug is given IV, whether</p> <p>12 it's NDMA or, you know, a -- an</p> <p>13 FDA-approved drug, giving it in the IV</p> <p>14 route, it does eventually, if it is</p> <p>15 metabolized in the liver, pass through</p> <p>16 the liver as part of its route of</p> <p>17 elimination.</p> <p>18 BY MR. VAUGHN:</p> <p>19 Q. If the liver is able to fully</p> <p>20 metabolize NDMA and systemic circulation takes</p> <p>21 less than five minutes, you wouldn't expect the</p> <p>22 half-life to be 13 minutes, would you?</p> <p>23 A. The issue that I have in being</p> <p>24 able to answer it to the best of my ability is</p> <p>25 that I'm not sure the first part of the question</p>
Page 31	Page 33
<p>1 day or how man- -- how long it takes for one</p> <p>2 cycle. So I know that's available information,</p> <p>3 but I don't have it off the top of my head.</p> <p>4 Q. Do you have an estimate, even?</p> <p>5 A. I know blood volume is</p> <p>6 approximately 5 liters. Typical cardiac output is</p> <p>7 about 3 to 4 liters per minute. So it -- it</p> <p>8 shouldn't take long. Less than ten minutes, maybe</p> <p>9 20 minutes. I can't verify that.</p> <p>10 Q. I mean, if -- if cardiac output</p> <p>11 is around 4 liters and blood volume is around 5</p> <p>12 liters, wouldn't you think that it goes all the</p> <p>13 way around the body in about a minute?</p> <p>14 A. Yeah, I don't think that's the</p> <p>15 case, though.</p> <p>16 Q. Okay. You think it might be less</p> <p>17 than 13 minutes, though?</p> <p>18 A. I --</p> <p>19 MR. FOWLER: Objection,</p> <p>20 we're -- we're -- calls for speculation.</p> <p>21 He's answered this.</p> <p>22 THE WITNESS: I really don't</p> <p>23 know. I'd have to look it up, because</p> <p>24 it's been a while since I've had to use</p> <p>25 that information.</p>	<p>1 is accurate. I think I would need to establish</p> <p>2 how long it takes.</p> <p>3 But remember the liver only gets</p> <p>4 part of -- of cardiac output. Part of cardiac</p> <p>5 output goes to other organs as well.</p> <p>6 Q. All right. Sitting here today,</p> <p>7 though, you have no idea how long it actually</p> <p>8 takes for the blood to go around the human body,</p> <p>9 do you?</p> <p>10 A. No. I -- I -- as of right now, I</p> <p>11 don't. I know the value if I were to -- to look</p> <p>12 it up, but I don't have it in front of me.</p> <p>13 Q. And that's not something you've</p> <p>14 looked into in forming your opinions for either of</p> <p>15 your expert reports that you've submitted in this</p> <p>16 litigation, correct?</p> <p>17 A. Correct. And -- and nor do I</p> <p>18 know the relevance that have any impact on my</p> <p>19 opinions anyway.</p> <p>20 MR. VAUGHN: All right. Melisha,</p> <p>21 let's go to his invoices.</p> <p>22 And this will be Exhibit 3. It</p> <p>23 is a composite exhibit of all of the</p> <p>24 invoices that were produced.</p> <p>25 (Exhibit 3 was marked.)</p>

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Page 35	Page 37
<p>1 MR. VAUGHN: All right. Let's go</p> <p>2 to page 3.</p> <p>3 BY MR. VAUGHN:</p> <p>4 Q. All right. Doctor, and do you</p> <p>5 see that you submitted a bill for eight hours of</p> <p>6 deposition time on September 1st, 2021?</p> <p>7 A. That should probably be November.</p> <p>8 So that's a typo.</p> <p>9 Q. Why should that be November?</p> <p>10 A. Based on the in- -- sorry?</p> <p>11 Q. Why should that be November?</p> <p>12 A. Oh, no. That -- is that the date</p> <p>13 that we did the previous deposition?</p> <p>14 Q. Well, we actually did the</p> <p>15 previous deposition on September 16th, which you</p> <p>16 also billed for.</p> <p>17 MR. VAUGHN: Melisha, if you want</p> <p>18 to go to page 5 on his invoices.</p> <p>19 BY MR. VAUGHN:</p> <p>20 Q. Now we have another bill for</p> <p>21 \$4,000 for an eight-hour deposition on September</p> <p>22 16th, 2021 also in Knoxville and the same start</p> <p>23 and end time.</p> <p>24 A. Yes. I understand now what</p> <p>25 happened. I sent an invoice to GT for the date of</p>	<p>1 September 16th, which was the date of the actual</p> <p>2 deposition, you also billed two-and-a-half hours</p> <p>3 for reviewing articles in advance of the</p> <p>4 deposition. So that's just the morning of the</p> <p>5 deposition you're billing?</p> <p>6 A. Correct.</p> <p>7 Q. Okay. And then the next one on</p> <p>8 October 6th, you note that you: "Preview/find</p> <p>9 Wang article for inclusion and articles</p> <p>10 considered."</p> <p>11 What does that mean?</p> <p>12 A. That I looked at those articles</p> <p>13 to see if I wanted to include them in my articles</p> <p>14 for consideration.</p> <p>15 Q. That was after you submitted your</p> <p>16 expert report and after you sat for deposition,</p> <p>17 correct?</p> <p>18 A. Correct.</p> <p>19 MR. VAUGHN: Let's go to page 7,</p> <p>20 Melisha.</p> <p>21 BY MR. VAUGHN:</p> <p>22 Q. All right, Doctor. Is this where</p> <p>23 you started working actually on your class action</p> <p>24 expert report?</p> <p>25 A. Correct.</p>
<p>1 the deposition, not knowing that that's not who</p> <p>2 should have received the invoice. So this invoice</p> <p>3 that I sent to GT was never paid.</p> <p>4 The other invoice was sent</p> <p>5 to -- I don't know which law firm, but they are</p> <p>6 the one who eventually paid that invoice. So I</p> <p>7 was not paid twice for that deposition.</p> <p>8 Q. Why is there a date inaccuracy of</p> <p>9 it being September 1st on page 3 of your invoice?</p> <p>10 A. Because I'm not very good at</p> <p>11 sometimes having the correct date on there.</p> <p>12 MR. VAUGHN: All right. Can we</p> <p>13 go to the next page, Melisha, page 4.</p> <p>14 BY MR. VAUGHN:</p> <p>15 Q. And on September 1st, on this</p> <p>16 bill, you also billed three-and-a-half hours for</p> <p>17 reviewing Lagana's deposition and conference call</p> <p>18 with counsel, correct?</p> <p>19 A. Correct.</p> <p>20 Q. Is that what you actually did</p> <p>21 then on September 1st instead of the deposition?</p> <p>22 A. Yes, because we just previously</p> <p>23 established that that was not the date of the</p> <p>24 deposition.</p> <p>25 Q. Okay. And then looking at</p>	<p>1 Q. And throughout this I note names</p> <p>2 Steve Fowler, Ken -- I'm not even going to try and</p> <p>3 pronounce that last name -- T. Harper. Are these</p> <p>4 all GT attorneys?</p> <p>5 A. Yes.</p> <p>6 Q. And is Greenberg Traurig, is that</p> <p>7 the law firm you were working with in generating</p> <p>8 this class action expert report?</p> <p>9 A. Yes.</p> <p>10 Q. Is that the only law firm that</p> <p>11 you were working with?</p> <p>12 A. Yes.</p> <p>13 Q. And you were providing opinions</p> <p>14 on bioequivalency studies of all of the Defendants</p> <p>15 in this litigation, correct?</p> <p>16 A. Yes. All that I received</p> <p>17 information on.</p> <p>18 Q. And GT, Greenberg Traurig, was</p> <p>19 the one responsible for giving you documents for</p> <p>20 each Defendant?</p> <p>21 MR. FOWLER: Objection, form.</p> <p>22 THE WITNESS: Yes.</p> <p>23 Every -- every document from</p> <p>24 manufacturers on ANDAs and</p> <p>25 bioequivalence studies that I received,</p>

<p style="text-align: right;">Page 38</p> <p>1 that came through GT. I did not deal 2 with any of the companies directly. 3 BY MR. VAUGHN: 4 Q. Or any of the other law firms? 5 A. Or any other law firms. 6 Q. And so if there were additional 7 documents that you wanted to review, Greenberg 8 Traurig attorneys would have been who you went to? 9 A. Yes. 10 Q. Were there documents that you 11 specifically asked to see, or is it just documents 12 that Greenberg Traurig gave you? 13 A. I asked GT to send me, from as 14 many of the manufacturers as they could, 15 bioequivalence studies that were used to file 16 and -- and received approval for their ANDAs. 17 And -- and then it was out of my hands what I 18 received at that point. It was up to the 19 companies to find and send me those reports 20 through GT. 21 Q. And so you would have expected 22 that all of the bioequivalency studies were given 23 to you, correct? 24 A. I don't expect that. I didn't 25 know what I was going to get. I just evaluated</p>	<p style="text-align: right;">Page 40</p> <p>1 manufacturers, instead of several thousand pages, 2 I only received the BE data only, and so I didn't 3 have to sift through for some of the situations a 4 lot more information than necessary for what I was 5 doing. 6 Q. Do you recall for which companies 7 that was? 8 A. Not off the top of my head, no. 9 Q. A second ago you testified that 10 the submission process is to include the BE data. 11 By that, do you mean that the company is supposed 12 to submit all of their bioequivalency data and 13 studies with their ANDA? 14 A. I believe that to be the case. 15 Q. And that's why you thought it was 16 appropriate just to review the ANDA for their 17 bioequivalency data, correct? 18 A. Well, or the bioequivalence data, 19 if that's all they sent me. I -- it was the 20 bioequivalence data that I was most interested in. 21 Q. And when you're talking about the 22 data, did you actually review the underlying data 23 or did you just review the final report? 24 A. It depends on the format that it 25 came to me. There was often a lot of underlying</p>
<p style="text-align: right;">Page 39</p> <p>1 what I did get. 2 Q. So I note typically on this you 3 note that you're reviewing ANDA files for 4 bioequivalency data. Why is it the ANDA files 5 that you're reviewing to find the bioequivalency 6 data? 7 A. It's -- the part of the ANDA 8 submission process is to include the -- the BE 9 data. So I would often get a file that had 50, 10 60, 70 folders in it, and I had to sift through 11 those and find the ones that actually had the 12 bioequivalence data in there. 13 So there's data on analytical, 14 the case report forms on all the volunteers who 15 were in the studies, what their lab values were, 16 their physical exam results. I mean, there was a 17 lot of information that's included, and it was 18 just the BE data that I was interested in sifting 19 through and finding. 20 Q. Each of those ANDAs are several 21 thousands of pages, correct? 22 A. Correct. 23 Q. And when you said -- 24 A. Just to add -- I'm sorry. Just 25 to add and see if it helps. For some of the</p>	<p style="text-align: right;">Page 41</p> <p>1 data. There were bioequivalence data in humans. 2 A lot of that had subject-by-subject what their 3 individual values were. Then it had summary data 4 on top of that. It just depended on the format in 5 which I received it. 6 Q. And did you look into the testing 7 methods that were employed in the different 8 bioequivalency studies? 9 A. In some of the more extensive 10 files that I received, there were testing data. 11 Q. And -- and for which 12 manufacturers did you have the more extensive 13 data? 14 A. Again, I'd have to go back 15 and -- and look at my files to make that kind of 16 accurate answer. 17 Q. Was it a majority or a minority 18 of the Defendants that you had extensive data on? 19 A. I'd say it was about half. So 20 when you look in my report to see which BE studies 21 I included, I'd say about half of those came from 22 looking at a lot of extensive information, and 23 some were a little bit more targeted towards just 24 the bioequivalence data. 25 MR. VAUGHN: Melisha, let's go to</p>

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1 the first page of those invoices again.
2 BY MR. VAUGHN:
3 Q. And I just want to run through
4 the billing amount, total billing amounts, Doctor.
5 So this first invoice was
6 \$26,000, correct?
7 A. Correct.
8 MR. VAUGHN: And second invoice,
9 Melisha, page 2.
10 BY MR. VAUGHN:
11 Q. This was \$42,250, correct,
12 Doctor?
13 A. Correct.
14 Q. And the third invoice was \$4,000,
15 correct?
16 A. Yes, but that may be the one that
17 did not get paid because I sent it to the wrong
18 firm for payment.
19 Q. And do you recall what firm you
20 sent that to?
21 A. I sent it to GT, and they sent it
22 to whatever firm was responsible for that.
23 Q. Then the next invoice is \$35,500,
24 correct?
25 A. Correct.

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1 Q. And the next invoice is \$4,000?
2 A. Again, that may be the overlap
3 with the other one. So both of those did not get
4 paid. One did; one didn't.
5 Q. Okay. And the next invoice is
6 for \$5,000?
7 A. Correct.
8 Q. And the next invoice is for
9 \$41,000?
10 A. Correct.
11 Q. And your final invoice is for
12 \$46,084, correct?
13 A. Correct.
14 Q. And my math shows that all those
15 together is \$204,000. If we drop that other
16 4,000, we're at \$200,000. Does that sound about
17 correct to you, Doctor?
18 A. That sounds right.
19 Q. And have they paid all of those
20 invoices to date?
21 A. Yes.
22 Q. And do you have additional time
23 that you have not billed, that is not reflected in
24 this billing?
25 A. No, I'm sorry. I'm sorry. The

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1 one you're on right now.
2 Q. Yeah, the last one?
3 A. I have not -- I have not been
4 paid for that one.
5 Q. Okay. And then do you have
6 outstanding time that you have not billed?
7 A. Yes. Between the end of last
8 week and up until today, I've not billed for that.
9 Q. And approximately how much time
10 is that?
11 A. Approximately, I'm going to say,
12 30 hours.
13 Q. And what were you doing during
14 those 30 hours?
15 A. Reviewing my report, reviewing
16 deposition transcripts of some of the Plaintiff
17 experts in this phase of the litigation,
18 rereviewing some of the articles that I thought
19 were most important to my conclusions.
20 I think that's the majority of
21 the work.
22 Q. How many meetings have you had
23 with counsel in preposit- -- preparation for this
24 deposition?
25 A. We met yesterday here in Atlanta,

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1 and we had three remote sessions between the end
2 of last week and the first part of this week.
3 Q. When you say "we," is that all
4 Greenberg Traurig attorneys?
5 A. Yes.
6 Q. Approximately how many hours
7 would you say those meetings were in total?
8 A. Maybe 16, 18 hours.
9 Q. And do you not charge Greenberg
10 Traurig more money for when you take a deposition
11 versus when you're just writing an expert report?
12 A. No, I don't charge differently.
13 Q. Let's go ahead and take a five,
14 ten-minute break.
15 MR. VAUGHN: Is that okay, Steve?
16 MR. FOWLER: Five minutes would
17 be good. But yeah, go ahead.
18 MR. VAUGHN: Sounds great.
19 Can we get a breakout room?
20 THE VIDEOGRAPHER: Yes.
21 The time is now 10:35 a.m. We're
22 now off the record.
23 (Brief recess observed.)
24 THE VIDEOGRAPHER: The time is
25 10:43. We're back on the record.

<p style="text-align: right;">Page 46</p> <p>1 MR. VAUGHN: All right, Melisha, 2 can we go back to Exhibit 1, 3 Dr. Bottorff's class action expert 4 report? And let's go to page 30. 5 BY MR. VAUGHN: 6 Q. And, Doctor, is this where you 7 begin discussing these bioequivalency studies of 8 the various Defendants? 9 A. Yes. 10 Q. All right. This first one that 11 you note is for Teva valsartan, and it's ANDA 12 090642, correct? 13 A. Correct. 14 Q. And those studies, you note, were 15 conducted in 2004, correct? 16 A. Correct. 17 Q. In your opinion, was Teva's 18 valsartan contaminated with nitrosamines in 2004? 19 A. I don't believe so, but I don't 20 know for sure. 21 Q. Is that something you asked 22 counsel? 23 A. No. 24 Q. Is that something you looked into 25 in any way at all?</p>	<p style="text-align: right;">Page 48</p> <p>1 MR. FOWLER: Objection to form. 2 THE WITNESS: Again, I don't know 3 if it was or wasn't, because 4 I've -- I've not traced company 5 documents about that kind of thing. 6 BY MR. VAUGHN: 7 Q. Right. I understand that 8 you're -- you do not know, Dr. Bottorff, but if 9 it's an "if-then" question. If it was not 10 contaminated, then this would not tell you 11 anything about if nitrosamines impact valsartan's 12 bioequivalency, correct? 13 A. In and of itself, no. 14 Q. Going down to line 496, you have 15 a sentence that reads: "The AUC and Cmax values 16 are expressed as geometric means rather than the 17 more common arithmetic means, since the 18 pharmacokinetic data are usually more log-normal 19 distributed, such that geometrics means giving 20 more accurate description of the central tendency 21 of the data." 22 Can you explain what that means 23 to me, Dr. Bottorff? 24 A. I -- I can as much as neither you 25 or I are not statisticians. But this is the</p>
<p style="text-align: right;">Page 47</p> <p>1 A. No. 2 Q. If Teva's valsartan in 2004 was 3 not contaminated with nitrosamines, how does this 4 study support that nitrosamines won't impact the 5 bioequivalency of valsartan? 6 A. In this particular case, I was 7 wanting to be thorough and include as many of the 8 bioequivalence studies as I could get and not 9 leave those out that -- for whatever reason or any 10 other reason. So I asked for all of them. And 11 every one of them that I got, I included in this 12 report. 13 Q. In the body of your expert 14 report, you included every single bioequivalency 15 study that was provided to you by Greenberg 16 Traurig? 17 A. That was provided to them by the 18 companies who were requested to send it to me, 19 yes. 20 Q. And so you would agree, though, 21 that if, in 2004, Teva's valsartan was not 22 contaminated with nitrosamines, this 23 bioequivalency study does not tell you if 24 nitrosamines will impact the bioequivalency of 25 valsartan, correct?</p>	<p style="text-align: right;">Page 49</p> <p>1 common way in which all of these bioequivalence 2 studies are conducted. It's expected in -- from 3 the FDA when these are submitted that they're 4 analyzed in that fashion. And it's done for the 5 reason that I list here, which has to do with how 6 the data are distributed across normal volunteers. 7 A lot of statistics are done 8 assuming that a negative value could be the same 9 as a positive value, which would lead to that 10 normal distribution in statistics. But when you 11 give a drug and measure AUC, it can only go up. 12 It can't go down. So that's part of this unequal 13 distribution that leads to this format of 14 demonstrating the central tendency using the --the 15 log-normal data. 16 I can describe how it's done, if 17 you want to know. 18 Q. You're not a statistician, are 19 you, Dr. Bottorff? 20 A. No, but I've had classes in 21 statistics and I've actually taught classes in 22 biostatistics. 23 Q. What is your prior experience 24 with bioequivalency studies? 25 A. My first bioequivalence study</p>

<p style="text-align: right;">Page 50</p> <p>1 experience was when I was a -- a -- a trainee in 2 my residency at the University of Kentucky, and I 3 worked in a unit that conducted these kind of 4 bioequivalence studies. And I've done some of my 5 own bioavailability studies where the conduct of 6 the trial is essentially the same.</p> <p>7 Q. What does geometrics mean? What 8 does that mean?</p> <p>9 A. Yeah. An arithmetic mean is you 10 take -- let's say we have three numbers, A, B, 11 and C. You take A plus B plus C, and then you 12 divide by three and that's the arithmetic means. 13 The geometrics mean is you multiply A times B 14 times C, and then you take the cube root of that 15 number.</p> <p>16 Q. And why does the geometric mean 17 then give a more accurate description of the 18 central tendency data?</p> <p>19 A. Well, that's where it gets beyond 20 my statistical understanding, other than it's 21 what's expected to be done in these kind of 22 studies, is they use the geometric instead of the 23 arithmetic mean.</p> <p>24 Q. Are you familiar with the term 25 "harmonic mean"?</p>	<p style="text-align: right;">Page 52</p> <p>1 level versus time data that go sort of up and 2 down, and you try to find the model that draws the 3 best fit through that data, each data point that's 4 not on that line -- as there's a difference 5 between the point and the line that's calculated. 6 And then the line is refit, the line is refit, and 7 you take the square of that difference between the 8 points in the line, and then you select the model 9 that gives you the least squares difference 10 between the predicted values and the observed 11 values.</p> <p>12 Q. Is there a difference between 13 least square means and geometric least square 14 means?</p> <p>15 A. No. I think that's a different 16 way of wording the same process that's done in 17 bioequivalence studies.</p> <p>18 Q. And what's going to give a more 19 accurate description of the central tendency of 20 data, a geometric mean or a geometric least 21 squares mean?</p> <p>22 A. It's the same thing.</p> <p>23 Q. Oh, those are interchangeable as 24 well?</p> <p>25 A. Those -- those are</p>
<p style="text-align: right;">Page 51</p> <p>1 A. Yes. There are -- there are 2 multiple ways of -- of displaying central 3 tendency. That's another one.</p> <p>4 Q. What is a harmonic mean?</p> <p>5 A. I've never used it, so I can't 6 define it for you off the top of my head.</p> <p>7 Q. What about a least squares mean?</p> <p>8 A. That's really part of these as 9 well, is because the FDA expects you, when you do 10 a comparison from drug A to drug B, to not give 11 everybody drug A first and drug B second. Some 12 people will get drug B first and drug A second. 13 And so you put that into a regression model along 14 with the means, and the regression model that 15 gives you the least difference, which is the least 16 squares fit to the data, are how you determine the 17 actual values that are going to be reported. So 18 it's part of the regression model.</p> <p>19 Q. What did you mean by "you put 20 that into a regression model along with means and 21 the regression model that gives you the least 22 difference"? What do you mean by "the model that 23 gives you the least difference"?</p> <p>24 A. Yeah. The -- the best way I can 25 describe it is if -- if you have average blood</p>	<p style="text-align: right;">Page 53</p> <p>1 interchangeable.</p> <p>2 Q. Thank you.</p> <p>3 MR. VAUGHN: All right. Let's go 4 to page 31 of his expert report now. 5 And looking down at the paragraph that 6 starts on line 508.</p> <p>7 BY MR. VAUGHN:</p> <p>8 Q. I like that you line number your 9 expert report, by the way. It makes it much 10 easier to go through.</p> <p>11 So this is the Princeton ANDA for 12 the valsartan 320 milligram, ANDA 204821, correct, 13 Doctor?</p> <p>14 A. Correct.</p> <p>15 Q. And the two studies that were 16 done here, there was a fasting study, H237-11. 17 What is a fasting study?</p> <p>18 A. Typically the FDA requires, when 19 you do these studies, to do one study in -- where 20 you dose in the morning after an overnight fast so 21 there's no food in the stomach, and then you 22 repeat the study with food in the stomach 23 to -- like after a standard breakfast kind of meal 24 to see if there's any effect of food altering the 25 bioavailability or the bioequivalence.</p>

<p>Page 54</p> <p>1 Q. And you note that these studies 2 were done in March and April of 2012. Did you 3 look into the manufacturing date of the product 4 that was actually tested in these bioequivalency 5 studies? 6 A. I -- I didn't for a -- a point of 7 record, but most of the files that I received, 8 there was a section you could go to and it would 9 talk about the date of actual production of what 10 was going to be called the test product, and they 11 even had the date of production of the -- of the 12 reference Diovan. And they would even often have 13 what the testing results on those individual 14 products were. 15 You know, if it said it had 16 320 milligrams, did it have 320 or right around 17 there? So those were often included in the 18 records that I reviewed. 19 Q. Do you recall approximately how 20 much earlier most of the manufacturing dates were 21 than study dates? Several months? 22 A. A few months. These are usually 23 batches that are not so large, because they want 24 to prove that they can demonstrate bioequivalence 25 with them before they go into more larger scale</p>	<p>Page 56</p> <p>1 studies on bioequivalency don't tell you anything 2 on if nitrosamines impact valsartan's 3 bioequivalency, correct? 4 A. Not by itself. 5 Q. And what do you mean by "not by 6 itself"? 7 A. Well, this report -- and I'm sure 8 we're going to keep going through it -- is going 9 to be leading to other bioequivalence studies with 10 some of the combination products where I 11 demonstrate that the addition into a valsartan 12 tablet of milligram quantities of other compounds 13 that do not have overlapping metabolic or 14 distribution pathways do not also alter the 15 bioequivalence. And so to me, it doesn't -- if it 16 is or isn't in there, it's not going to alter the 17 bioequivalence pattern. 18 Q. About line 513, you discuss 19 Hetero Labs' ANDA 203311 and Studies 20 10-VIN -- V-I-N -- -337 and Study 330-VALS-2011, 21 and you note that these studies were conducted in 22 February and July of 2011, correct? 23 A. Correct. 24 Q. And do you know if Hetero Labs' 25 valsartan was contaminated with nitrosamines in</p>
<p>Page 55</p> <p>1 production. 2 Q. Do any additional tests related 3 to bioequivalency have to be done when a company 4 scales up production? 5 A. I know there are times. The 6 majority of these, the FDA requires the in-human 7 bioequivalence study to be done on the largest 8 tablet size that you're going to market. That's 9 why these are almost always in the 320 milligram 10 dosage. And then you're allowed to do in vitro 11 dissolution testing with the smaller doses. 12 So even though the bioequivalence 13 study might have been done with the 320, the ANDA 14 got approved for 40, 80, 160, as well as the 320. 15 And that was often done based on dissolution 16 testing. So when you upscale, you can often 17 demonstrate bioequivalence using the dissolution 18 testing rather than repeat your human trial at 19 that point. 20 Q. And do you know if Princeton's 21 valsartan was contaminated prior to March of 2012? 22 A. I don't specifically know that. 23 Q. And, again, if Princeton's 24 valsartan was not contaminated with nitrosamines 25 at the time of this study, then this -- these</p>	<p>Page 57</p> <p>1 2011? 2 A. Again, I don't. It -- it's my 3 understanding that some of these generic 4 manufacturers were making their drug with a 5 process that may have had nitrosamines in it and 6 they didn't know it. So I can't tell you with 7 each company where that was and when that 8 happened. I -- I'm somewhat certain that some of 9 these did and it wasn't known, but it still didn't 10 alter the bioequivalence. 11 Q. And so is it your testimony today 12 that Hetero Labs' valsartan might have been 13 contaminated with nitrosamines dating back to at 14 least 2011? 15 A. It is my testimony that I don't 16 know which companies may have had it, but that I'm 17 suspicion [sic] -- my suspicion is that some did, 18 and I don't know which. 19 Q. All right. Go to page 32, line 20 517. You are now discussing a Torrent 21 Pharmaceuticals' ANDA 202728 with Studies 22 PK-09-100 and Study PK-09-103. These are on 23 valsartan 320 milligrams, and you note that the 24 studies were done in July of 2010, correct? 25 A. Yes.</p>

<p style="text-align: right;">Page 58</p> <p>1 Q. And Torrent's valsartan, is it 2 your opinion that it was contaminated with 3 nitrosamines back in 2010? 4 A. It is my opinion that I don't 5 know if it was or not. 6 Q. And if Torrent's valsartan was 7 not contaminated with nitrosamines back in 2010, 8 these bioequivalency studies don't tell you 9 anything in relation to if nitrosamines impact the 10 bioequivalency of valsartan, correct? 11 A. And, again, as I said before, not 12 in and of themselves. But as we keep working 13 through this, you'll see one of the premises about 14 having combination products with more than 15 valsartan, like hydrochlorothiazide in 16 six-and-a-half -- or six-and-a-quarter up to 25 17 milligrams, amlodipine 5 or 10 milligrams, having 18 no effect on the bioequivalence of -- of valsartan 19 because of a lack of overlapping metabolic 20 pathways. 21 And so as I've -- I've 22 demonstrated in both reports, the lack of an 23 overlapping metabolic pathway between the 24 nitrosamines and valsartan, that there would be no 25 reason, and in fact there couldn't be any reason,</p>	<p style="text-align: right;">Page 60</p> <p>1 limits are to demonstrate that they remained 2 within the FDA guidelines of the confidence limits 3 being allowed to be as low as 80 percent or as 4 high as 125 percent. 5 Q. So does that mean that -- 6 A. That would be for the A- -- I'm 7 sorry. Whether that be for the AUC value or the 8 Cmax value. 9 Q. And so does that mean that 10 10 percent of the population is allowed to fall 11 outside of the 80 percent to 125 percent range? 12 A. No, that's not what it means. 13 Q. Can you explain further? 14 A. Sure. What it means is that if 15 you were to redo this experiment 100 times, 90 16 times you would still get values that are between 17 that range of upper and lower limit. So it's more 18 of a statistical value than a what-happened- 19 to-a-patient value. 20 Q. I understand now. I appreciate 21 that clarification. 22 And so on the PK-09-103, it's 23 getting up to 123.65 percent, and that's okay 24 because it's less than 125, correct? 25 A. Correct. That's the upper limit</p>
<p style="text-align: right;">Page 59</p> <p>1 to have that have any effect on the bioequivalence 2 of valsartan. 3 Q. What were the two combination 4 drugs that you just mentioned? Amlodipine and 5 what was it? 6 A. Hydrochlorothiazide. Those are 7 the components of the brand name Exforge or 8 Exforge HCT. 9 Q. Are either of those drug 10 genotoxic -- genotoxins? 11 A. No. 12 Q. Are nitrosamines genotoxins? 13 A. In animals, yes, depending on the 14 exposure level. 15 Q. All right. On the PK-09-103 16 Study, on that far right-hand column, it says: 17 "90 percent C.I." 18 What does the C.I. mean? 19 A. It's a confidence interval. The 20 90 percent confidence interval around that value 21 in the column before it, which is the percentage 22 similarity between the brand name and the test 23 product. So it's a -- an -- the average value 24 with the 90 percent confidence limits around that 25 value. And these are to -- these confidence</p>	<p style="text-align: right;">Page 61</p> <p>1 of the FDA's guidelines for demonstrating 2 bioequivalence. 3 MR. VAUGHN: Let's go to page 33, 4 Melisha. 5 BY MR. VAUGHN: 6 Q. All right. Line 537 and 538, you 7 note that: "HCTZ" -- and what's HCTZ? 8 A. Hydrochlorothiazide. 9 Q. Is it okay if I refer to it as 10 HCTZ in the deposition? 11 A. For me it is. 12 Q. Appreciate it. 13 You note that: "HCTZ is 14 primarily eliminated through the kidney," correct? 15 A. Correct. 16 Q. And then you say: "Therefore, 17 HCTZ would have no pharmacokinetic or 18 pharmacodynamic overlap with valsartan or NDMA or 19 NDEA," correct? 20 A. Correct. 21 Q. And why is that? 22 A. Well, there's multiple parts to 23 that question. I previously demonstrated how 24 valsartan is absorbed, taken up into the liver, 25 excreted in bile and has a mild cytochrome P450</p>

<p style="text-align: right;">Page 62</p> <p>1 pathway of elimination. None of those are shared 2 by Hydrochlorothiazide. None of those are shared 3 by NDMA or NDEA. 4 And I guess I should add that's 5 the pharmacokinetic reason for no overlap. The 6 pharmacodynamic reason is that -- that gets to 7 their mechanism of action. How does 8 Hydrochlorothiazide lower blood pressure? Not the 9 same way that valsartan does. So there's no 10 overlap between their -- their blood pressure 11 effects. So that would be a lack of a 12 pharmacodynamic-shared mechanism. 13 Q. And so is part of the reason that 14 there's no overlap is they're being metabolized in 15 different organs? 16 A. Well, that's part of it. Part of 17 it can be you're metabolized in the same organ but 18 by a different pathway. You would still then have 19 no overlap. 20 Q. And NDMA is metabolized, in your 21 opinion, in the liver, correct? 22 A. And how it's given and how much 23 dose is -- is given. 24 Q. The NDMA that has been 25 contaminated in valsartan, it's your opinion that</p>	<p style="text-align: right;">Page 64</p> <p>1 Q. And is -- 2 A. Different from valsartan, 3 separate from NDMA. 4 Q. Thank you. You knew my next 5 question. 6 Now, I don't see that you gave an 7 opinion like you did with HCTZ that it would have 8 no pharmacokinetic [sic] or pharmacodynamic [sic] 9 overlap with valsartan or NDMA/NDEA. 10 Is that also your opinion, 11 though, with amlodipine? 12 A. Yes. I -- I say the same thing 13 in the next sentence, but in a slightly different 14 way, because there's no identified mechanism of 15 drug interaction or no overlapping route of 16 metabolism. 17 Q. Can liver cirrhosis impact the 18 metabolism of any of these drugs? 19 A. Not in a predictable fashion. 20 Q. What do you mean by that? 21 A. Well, there are probably maybe as 22 many as 100 or 150 different cytochrome P450 23 pathways. Some of them have been studied for 24 alterations in cirrhosis; some have not. Most do 25 not show a change in their metabolic capability in</p>
<p style="text-align: right;">Page 63</p> <p>1 it's metabolized in the liver, correct? 2 A. When ingested orally, yes. 3 Q. And valsartan itself is also 4 metabolized in the liver, correct? 5 A. By a different metabolic pathway 6 entirely. 7 Q. And is that the P450 pathway that 8 you were just mentioning? 9 A. Well, there's a P450 pathway for 10 NDMA that's separate and distinct from the minor 11 P450 pathway with valsartan. 12 Q. But they're both metabolized 13 through a P450 pathway, correct? 14 A. Correct, but a separate and 15 distinct different P450 pathway. 16 Q. And then line 545 you note that: 17 "Amlodipine is primarily hepatically metabolized." 18 And that means metabolized by the 19 liver as well, correct? 20 A. Yes. 21 Q. And -- I'm -- 22 A. Again, by a distinct metabolic 23 pathway called 3A4. 24 Q. P450, 3A4? 25 A. Yes.</p>	<p style="text-align: right;">Page 65</p> <p>1 cirrhosis. 2 Q. So liver damage could impact the 3 metabolism of these drugs? 4 MR. FOWLER: Object to form. 5 THE WITNESS: It's probably been 6 studied and there's other types of liver 7 damage from cirrhosis, so it can't be 8 yes/no. You have to look at the type of 9 liver damage and the specific P450 10 pathway to see what's actually been 11 demonstrated or shown not to have an 12 effect. But it can't be done as a 13 blanket statement. 14 BY MR. VAUGHN: 15 Q. Do you have an opinion as to what 16 type of liver damage would impact the metabolism 17 of any of these drugs the most? 18 MR. FOWLER: Objection: Form, 19 foundation. 20 THE WITNESS: I don't. As I said 21 before, it's not something you can say 22 in a blanket yes/no format. So you'd 23 have to literally look at each pathway 24 and the multiple different types of 25 hepatic disease to see what's been done</p>

<p style="text-align: right;">Page 66</p> <p>1 and what's not been done.</p> <p>2 MR. VAUGHN: Let's go to page 34,</p> <p>3 Melisha.</p> <p>4 BY MR. VAUGHN:</p> <p>5 Q. And at 559, we're now at the</p> <p>6 section on Exforge. What is Exforge?</p> <p>7 A. That's the brand name of the</p> <p>8 combination product of valsartan and amlodipine</p> <p>9 made by Novartis.</p> <p>10 Q. Okay. So when one of the</p> <p>11 companies is doing their bioequivalency studies on</p> <p>12 valsartan plus amlodipine, they do it in</p> <p>13 comparison to Exforge?</p> <p>14 A. Correct.</p> <p>15 Q. And line 562, you are now</p> <p>16 discussing Aurobindo's ANDA 206512, and within</p> <p>17 that, their Study No. 368-12 and 369-12. And you</p> <p>18 note that these were done in October of 2013,</p> <p>19 correct?</p> <p>20 A. Correct.</p> <p>21 Q. And you don't recall the date of</p> <p>22 manufacture of the generic pills that were being</p> <p>23 tested, do you?</p> <p>24 A. No. Again, they would have been</p> <p>25 within some, usually few months time frame, but I</p>	<p style="text-align: right;">Page 68</p> <p>1 A. Again, it -- it can't. There's</p> <p>2 no mechanism for it to do such. This, again,</p> <p>3 study in and of itself is demonstrating that by</p> <p>4 showing that you still get all the valsartan</p> <p>5 you're supposed to get, even when amlodipine is</p> <p>6 present, because it doesn't share a metabolic</p> <p>7 pathway.</p> <p>8 Q. Did you even need to look at any</p> <p>9 of these bioequivalency studies, as you had</p> <p>10 already determined that there's no way that</p> <p>11 nitrosamines can impact the bioequivalency of the</p> <p>12 drugs?</p> <p>13 A. Well, the -- the process that I</p> <p>14 went through was not starting with that. I first</p> <p>15 had to go through the metabolic pathways of these</p> <p>16 various components and then look at the</p> <p>17 bioequivalence studies and then draw my conclusion</p> <p>18 at the end of that, not on the front end of that.</p> <p>19 Q. And you think that studies done</p> <p>20 without nitrosamines can tell you if nitrosamines</p> <p>21 are going to impact the bioequivalency?</p> <p>22 MR. FOWLER: Objection: Form,</p> <p>23 mischaracterizes.</p> <p>24 THE WITNESS: Again, I think in</p> <p>25 answering that previously, I -- I said</p>
<p style="text-align: right;">Page 67</p> <p>1 don't know.</p> <p>2 Q. Okay. So is it your opinion that</p> <p>3 Aurobindo's valsartan was contaminated with</p> <p>4 nitrosamines prior to October of 2013?</p> <p>5 A. It is my testimony that I do not</p> <p>6 know, but that it may have had. And that if it</p> <p>7 did, it didn't alter the bioequivalence anyway.</p> <p>8 Q. And if it -- if that -- scratch</p> <p>9 that.</p> <p>10 And if Aurobindo's valsartan was</p> <p>11 not contaminated with nitrosamines during this</p> <p>12 time, then these bioequivalency studies don't tell</p> <p>13 you anything as to if nitrosamines will impact the</p> <p>14 bioequivalency of valsartan plus amlodipine,</p> <p>15 correct?</p> <p>16 A. Well, no, not necessarily</p> <p>17 correct. Because, again, in microgram quantities,</p> <p>18 without any overlapping mechanism for an</p> <p>19 interaction, there's no reason to expect that</p> <p>20 there would be any impact at all.</p> <p>21 Q. But if this study is testing</p> <p>22 pills without any nitrosamines in it, how does</p> <p>23 that add anything? How does that support your</p> <p>24 opinion that the nitrosamines aren't going to</p> <p>25 impact the bioequivalency?</p>	<p style="text-align: right;">Page 69</p> <p>1 that not in and of themselves. You have</p> <p>2 to look at the whole picture. And part</p> <p>3 of the whole picture is valsartan's</p> <p>4 bioequivalence is retained in the</p> <p>5 presence of other compounds, that I had</p> <p>6 to see the data for, before I could draw</p> <p>7 that conclusion.</p> <p>8 And then also understanding that</p> <p>9 some of these probably had nitrates in</p> <p>10 them, even as far back as -- as when</p> <p>11 these bioequivalence studies were done.</p> <p>12 BY MR. VAUGHN:</p> <p>13 Q. You just testified that you have</p> <p>14 to look at the whole picture. What do you mean by</p> <p>15 "the whole picture"?</p> <p>16 A. Look at all the compounds</p> <p>17 involved, their metabolic pathways, the</p> <p>18 bioequivalence studies.</p> <p>19 Q. All of the bioequivalency</p> <p>20 studies?</p> <p>21 A. All that I received, which</p> <p>22 supported my contention and the -- all of the</p> <p>23 metabolic pathways of all the compounds involved.</p> <p>24 Q. If there were other</p> <p>25 bioequivalency studies that you did not receive,</p>

<p>Page 70</p> <p>1 you wouldn't have the whole picture, would you?</p> <p>2 A. I wouldn't have any more</p> <p>3 information than what I've already put in my</p> <p>4 report, but I think there's adequate information</p> <p>5 in my report to make my conclusions.</p> <p>6 Q. If there were bioequivalency</p> <p>7 studies that -- scratch that.</p> <p>8 If some of the generic</p> <p>9 manufacturers conducted bioequivalency studies on</p> <p>10 their valsartan and they failed the bioequivalency</p> <p>11 studies, you would then ex- -- you would have</p> <p>12 expected the Defense attorneys would have given</p> <p>13 you that information, correct?</p> <p>14 A. And they did.</p> <p>15 Q. How do you know they did?</p> <p>16 A. I saw one bioequivalence study</p> <p>17 that the average AUC value and the average Cmax</p> <p>18 value, you know, the two primary determinates of</p> <p>19 rate and extent of absorption, were within the</p> <p>20 FDA's requirements, but the confidence limits</p> <p>21 exceeded the requirements.</p> <p>22 Q. What do you mean by "exceeded"?</p> <p>23 A. So I did see a study --</p> <p>24 Q. Sorry, continue.</p> <p>25 A. So I did see -- I did see a study</p>	<p>Page 71</p> <p>1 that failed the FDA's bioequivalence standards and</p> <p>2 the company did a root cause analysis -- I don't</p> <p>3 remember which one it was right now -- and found</p> <p>4 that it was a -- a change in the size of the</p> <p>5 microparticles when they did the tableting, and so</p> <p>6 they went back and reformulated the tablet and</p> <p>7 redid a bioequivalence study -- and its one of the</p> <p>8 ones that's in here -- that then met the FDA</p> <p>9 standards after the reformulation.</p> <p>10 Q. You don't recall what company</p> <p>11 that is?</p> <p>12 A. I don't. I'd have to go back and</p> <p>13 look through all those files again.</p> <p>14 Q. Do you know what -- if they're</p> <p>15 API?</p> <p>16 A. Again, I -- I don't know off the</p> <p>17 top of my head whether they made their own or</p> <p>18 whether they purchased it.</p> <p>19 Q. You don't know if they were</p> <p>20 getting their API from ZHP?</p> <p>21 A. I don't, off the top of my head.</p> <p>22 Q. And do you happen to know if</p> <p>23 wherever they were getting their API from sent</p> <p>24 them the same API later on that they passed their</p> <p>25 bioequivalency study with?</p>	<p>Page 72</p> <p>1 A. I seem to recall that they were</p> <p>2 using the same API. It was more the tableting</p> <p>3 process that needed to be revised.</p> <p>4 Q. Was it the size of the granules</p> <p>5 of the valsartan API that was causing the</p> <p>6 bioequivalency studies to fail?</p> <p>7 A. No. It was the size of the</p> <p>8 particles that are used as part of the tableting</p> <p>9 process. So, yes, valsartan was in that particle,</p> <p>10 and I don't know whether there was NDMA in there</p> <p>11 or not. But based on the internal report for that</p> <p>12 company, it had nothing to do with the API; it was</p> <p>13 the tableting process.</p> <p>14 Q. What are you basing that on,</p> <p>15 the -- it's the tableting process and not the API?</p> <p>16 A. Their own internal root cause</p> <p>17 analysis.</p> <p>18 Q. But you can't point me to which</p> <p>19 Defendant you're discussing or the document that</p> <p>20 you're relying on?</p> <p>21 A. I could. It might take me two or</p> <p>22 three hours to sift through the files.</p> <p>23 Q. That's okay. I think we'll</p> <p>24 probably get to it later.</p> <p>25 MR. VAUGHN: Let's go to page 36,</p>	<p>Page 73</p> <p>1 Melisha, and start on line 586.</p> <p>2 BY MR. VAUGHN:</p> <p>3 Q. All right. We're talking about</p> <p>4 Torrent's ANDA 202377. And so this would, again,</p> <p>5 be the valsartan plus amlodipine, correct?</p> <p>6 A. Yes.</p> <p>7 Q. And the bioequivalency studies</p> <p>8 within this ANDA is PK-09-192, PK-09-193 and</p> <p>9 PK-10-023, and you note that these were conducted</p> <p>10 between May and July of 2010, correct?</p> <p>11 A. Yes.</p> <p>12 Q. Is it your opinion that Torrent's</p> <p>13 valsartan was contaminated with nitrosamines in</p> <p>14 May of 2010?</p> <p>15 A. Again, it may have been. I -- I</p> <p>16 do not know.</p> <p>17 Q. And so, again, if Torrent's</p> <p>18 valsartan was not contaminated with nitrosamines</p> <p>19 in 2010, then these studies don't actually tell</p> <p>20 you anything specifically on if nitrosamines</p> <p>21 impact the bioequivalency of valsartan plus</p> <p>22 amlodipine, correct?</p> <p>23 A. Again, not in and of itself,</p> <p>24 but -- but if it did contain it, then it does tell</p> <p>25 you that.</p>
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<p style="text-align: right;">Page 74</p> <p>1 Q. But you have no idea if Torrent's 2 valsartan was contaminated back in 2010 with 3 nitrosamines, do you? 4 MR. FOWLER: Asked and answered. 5 THE WITNESS: I -- I do not know. 6 BY MR. VAUGHN: 7 Q. Do you know what the purpose was 8 of them doing two fasting studies at different 9 milligrams? 10 A. I -- I don't. I don't recall 11 seeing why that selection was made. Again, I know 12 they're required by the FDA to do the highest 13 dose. I don't know why they chose the 160 in 14 addition, so I -- I really don't know. I 15 certainly don't recall seeing in the documents I 16 had access to, that it was explained. 17 Q. Is there any reason why on the 18 fed study the bioequivalency range is on the low 19 end and on the fasting studies it's on the high 20 end? 21 MR. FOWLER: Objection to form. 22 THE WITNESS: I do believe that 23 it's been reported that there's a small 24 reduction in systemic exposure to 25 valsartan when taken with food compared</p>	<p style="text-align: right;">Page 76</p> <p>1 only capable of being different because 2 of a function of being fed or not. 3 BY MR. VAUGHN: 4 Q. Do you -- in relation to 5 valsartan, do you have an opinion if fasting or 6 fed bioequivalency studies are harder to pass? 7 A. I have no opinion that they're 8 any harder to pass. 9 MR. VAUGHN: All right. Page 37. 10 BY MR. VAUGHN: 11 Q. All right. In the Comparison 12 part now is Diovan HCT. Is HCT the same as HCTZ? 13 A. Yes. Novartis, in their branded 14 name, they don't use all four letters. They just 15 use three of them. Whereas in the generic 16 pharmacology vernacular, we always use the four 17 letters of HCTZ. 18 Q. Okay. And so this section is now 19 on the combination of valsartan plus HCTZ pills, 20 correct? 21 A. Correct. 22 Q. And this is Aurobindo ANDA 202519 23 that you're discussing in this paragraph, correct? 24 A. Yes. 25 Q. And the studies within that ANDA</p>
<p style="text-align: right;">Page 75</p> <p>1 to not being taken with food. But then 2 it's in the package label that 3 the -- that small reduction is of -- not 4 of any clinical significance. And so 5 patients in the package labels are 6 instructed that they can take it with or 7 without food and it won't alter the 8 ultimate response to the drug. 9 BY MR. VAUGHN: 10 Q. That small reduction in systemic 11 exposure to valsartan when taken with food, that 12 should be the same for the brand name and the 13 generic, correct? 14 A. Yes. 15 Q. Then why is the generic low on 16 the fed studies but high on the fasting studies? 17 MR. FOWLER: Objection, form. 18 THE WITNESS: I don't think it's 19 only because of whether it's fed or not 20 fed. I think tablet performance, if you 21 go back and look through some of these, 22 some manufacturers, even in a fasting 23 state, their AUCs are a little higher 24 than Diovan and some are a little lower 25 than Diovan. So it -- it's not purely</p>	<p style="text-align: right;">Page 77</p> <p>1 are 304-09 and 305-09. And you note that those 2 were conducted -- well, actually, you don't know 3 what year those were conducted, do you? 4 A. Yeah, I don't know why I didn't 5 put that in there. I tried to be consistent 6 in -- in including the actual dates. And so I 7 don't know if I received only a summary report 8 that didn't have them. 9 What I could do, though, is go to 10 the FDA's website and put in the ANDA number, and 11 you can get from the website the date that the FDA 12 approved the ANDA. So I did have that. 13 Q. Based on Aurobindo's naming 14 structure of their studies, does that -09 indicate 15 anything to you? 16 A. I can't say that I paid attention 17 to whether that was a 09, like 2009 study or not, 18 so I don't know for sure. It may have been the 19 ninth production product or -- you know, I have no 20 idea. 21 Q. Or a 2009 manufacturing date of 22 the product? 23 A. Could have been. 24 Q. Well, let's just assume, then, 25 that this was done in 2010. If this was done in</p>

<p>Page 78</p> <p>1 2010, do you have an opinion as to if Aurobindo's 2 valsartan was contaminated with nitrosamines? 3 A. I don't know. It may have. 4 Q. And if the ANDA wasn't approved 5 until March of 2013, the studies were definitely 6 done in advance of that, correct? 7 A. They were definitely done in 8 advance of 2013, yes. For sure. 9 Q. And the manufacturing date of the 10 valsartan would have been even earlier than the 11 bioequivalency studies, correct? 12 A. By some, usually, a few months 13 time frame. 14 Q. And so you're unaware if the 15 product tested in these bioequivalency studies was 16 contaminated with nitrosamines, correct? 17 MR. FOWLER: Asked and answered. 18 THE WITNESS: Correct, I'm 19 unaware of that. They may have been. 20 BY MR. VAUGHN: 21 Q. And if Aurobindo's valsartan was 22 not contaminated with nitrosamines at the time 23 that these studies were being conducted, these 24 bioequivalency studies don't actually tell you 25 anything on if nitrosamines impact the</p>	<p>Page 80</p> <p>1 the bioequivalence. And -- and if I recall from 2 having read one of Plaintiff expert's depositions, 3 Dr. Najafi, I believe, I think he said the same 4 thing. It didn't matter whether it was in there 5 or not; it wouldn't have affected the 6 bioequivalence. 7 Q. If there are bioequivalency 8 studies that were conducted on valsartan that was 9 known to be contaminated, would you want to review 10 those studies? 11 A. Of course if I had them, I would 12 review them. 13 Q. Would you give more weight to the 14 studies that had no nitrosamines impurities in 15 them versus ones that did have nitrosamines 16 impurities in them? 17 A. No, because they're not going to 18 show any difference, so it wouldn't have any 19 difference to me at all. Wouldn't change my 20 conclusion, it would only support my conclusion. 21 Q. And so without looking at the 22 studies, you can already determine that they're 23 not going to show any difference? 24 A. To the best of our scientific 25 capability through mechanisms whereby there would</p>
<p>Page 79</p> <p>1 bioequivalency of the valsartan plus HCTZ, 2 correct? 3 A. And, again -- and the same if 4 they do. 5 But without an overlapping 6 mechanism, it doesn't matter whether it's in there 7 or not. 8 Q. And so none of these studies that 9 we've looked at actually matter to you, do they, 10 because you don't know if any of them have 11 nitrosamines in the drug product? 12 MR. FOWLER: Objection to form. 13 THE WITNESS: No, that's not what 14 I said about them not mattering. I'm 15 saying whether NDMA was in there or not 16 doesn't matter because the 17 bioequivalence would be retained. 18 BY MR. VAUGHN: 19 Q. So in your expert opinion, it 20 doesn't matter if the study is using a drug 21 product with nitrosamines in order to figure out 22 if nitrosamines impact the bioequivalency of the 23 drug? 24 A. It is my expert opinion that 25 whether they were in there or not would not affect</p>	<p>Page 81</p> <p>1 be an effect on bioequivalence, and those 2 mechanisms do not exist. 3 MR. VAUGHN: All right. Go on to 4 page 38. 5 BY MR. VAUGHN: 6 Q. All right. And you're now 7 discussing at line 613 Princeton ANDA 206083. And 8 again, this is for valsartan plus HCTZ, correct, 9 Doctor? 10 A. Yes. 11 Q. And within the ANDA you note 12 bioequivalency studies H052-12 and H053-12, and 13 you note that these were both done in 2012, 14 correct? 15 A. Yes. 16 Q. And do you have any opinion on if 17 Princeton's valsartan plus HCTZ was 18 contaminat- -- contaminated with nitrosamines in 19 2012? 20 A. I don't personally know that. 21 They may have been. 22 Q. And if Princeton's valsartan was 23 not contaminated with nitrosamines in 2012, these 24 studies don't actually tell you if nitrosamines 25 are going to impact the bioequivalency of</p>

<p>Page 82</p> <p>1 Princeton's valsartan plus HCTZ, correct?</p> <p>2 A. Correct, in that -- in and of</p> <p>3 itself. But, again, with the presence of</p> <p>4 milligram quantities compared to NDMA microgram</p> <p>5 quantities, without overlapping mechanisms, it</p> <p>6 adds to the body of -- of my knowledge that</p> <p>7 there's no reason to expect that NDMA would have</p> <p>8 any effect on bioequivalence at all.</p> <p>9 Q. Okay. And in the paragraph</p> <p>10 starting at line 622, you are discussing ANDA</p> <p>11 091654, which is for Torrent's valsartan plus</p> <p>12 HCTZ, correct?</p> <p>13 A. Yes.</p> <p>14 Q. And then you note Studies</p> <p>15 PK-09-23 and PK-09-024, and you note that these</p> <p>16 bioequivalency studies were conducted in March of</p> <p>17 2009, correct?</p> <p>18 A. Yes.</p> <p>19 Q. And do you have any opinion if</p> <p>20 Torrent's generic valsartan plus HCTZ was</p> <p>21 contaminated with nitrosamines back in 2009?</p> <p>22 A. I do not know. It may have been.</p> <p>23 Q. And if Torrent's valsartan plus</p> <p>24 HCTZ was not contaminated with nitrosamines back</p> <p>25 in 2009, then these bioequivalency studies don't</p>	<p>Page 84</p> <p>1 Here's our bioequivalence result for Diovan/HCT</p> <p>2 versus our equivalent product.</p> <p>3 And so it -- I may have in some</p> <p>4 cases had a much more limited amount of</p> <p>5 information that came with the file that had the</p> <p>6 BE data in it.</p> <p>7 Q. And so for some of the files, you</p> <p>8 were not able to review all the data, correct?</p> <p>9 A. I was able to review the relevant</p> <p>10 bioequivalence data, yes.</p> <p>11 Q. And the Mylan studies, that you</p> <p>12 were discussing in this paragraph, you note were</p> <p>13 conducted in May of 2005, correct?</p> <p>14 A. Yes, I did have that information.</p> <p>15 Q. And did you have any information</p> <p>16 on if Mylan's valsartan plus HCTZ was contaminated</p> <p>17 with nitrosamines back in 2005?</p> <p>18 A. I have no knowledge of that. It</p> <p>19 may have been.</p> <p>20 Q. Your opinion today is that</p> <p>21 Mylan's valsartan might have been contaminated</p> <p>22 going all the way back to 2005?</p> <p>23 A. Do not know.</p> <p>24 Q. And if Mylan's valsartan plus</p> <p>25 HCTZ was not contaminated back in 2005, then these</p>
<p>Page 83</p> <p>1 actually tell you anything on if nitrosamines</p> <p>2 impact the bioequivalency of valsartan plus HCTZ,</p> <p>3 correct?</p> <p>4 A. Correct, to a certain degree.</p> <p>5 But, again, without the overlapping mechanisms and</p> <p>6 the fact that it may have had it in there, then</p> <p>7 I -- I don't think this is changing my conclusion</p> <p>8 at all.</p> <p>9 MR. VAUGHN: Page 39.</p> <p>10 BY MR. VAUGHN:</p> <p>11 Q. All right. Paragraph starting</p> <p>12 line 626, you note Mylan data on bioequivalency</p> <p>13 studies comparing generic valsartan/HCTZ to</p> <p>14 Diovan/HCT, but you don't reference an ANDA on</p> <p>15 this one.</p> <p>16 Is there a reason for that?</p> <p>17 A. It was either not identified in</p> <p>18 the files that I received or that I could not find</p> <p>19 it directly at the FDA website to put a specific</p> <p>20 ANDA number in.</p> <p>21 Q. What do you mean by "not</p> <p>22 identified in the files" you received?</p> <p>23 A. As I said before, some of these</p> <p>24 files I received were very lengthy and very</p> <p>25 comprehensive, and some of them I received were:</p>	<p>Page 85</p> <p>1 bioequivalency studies don't actually tell you</p> <p>2 anything on if nitrosamines impact the</p> <p>3 bioequivalency of valsartan plus HCTZ, correct?</p> <p>4 A. They indirectly do, as I -- as</p> <p>5 I've stated before, because milligram quantities</p> <p>6 of HCTZ without an overlapping mechanism do not</p> <p>7 alter valsartan. So there would be no reason to</p> <p>8 expect that microgram quantities of NDMA or NDEA,</p> <p>9 without overlapping mechanisms, would have any</p> <p>10 effect on the bioequivalence.</p> <p>11 So I -- I don't change my</p> <p>12 conclusion at all.</p> <p>13 Q. Does that meet FDA guidance, that</p> <p>14 just if there's not a known overlapping mechanism,</p> <p>15 that you don't need to do bioequivalency studies?</p> <p>16 MR. FOWLER: Objection: Form,</p> <p>17 foundation.</p> <p>18 THE WITNESS: The FDA requires</p> <p>19 the bioequivalence studies irrespective</p> <p>20 of whether they do or do not have</p> <p>21 impurities in them.</p> <p>22 BY MR. VAUGHN:</p> <p>23 Q. If a drug has a different</p> <p>24 chemical in it, even if it's an excipient, does</p> <p>25 the FDA require additional bioequivalency studies?</p>

<p style="text-align: right;">Page 86</p> <p>1 MR. FOWLER: Objection, form. 2 THE WITNESS: Make sure I'm 3 understanding. Are you asking if two 4 products have different excipients of 5 the same active ingredient, would it 6 require a bioequivalence study? 7 BY MR. VAUGHN: 8 Q. Yeah. If a generic drug that 9 already passed bioequivalency studies added a new 10 excipient, would the FDA require additional 11 bioequivalency studies? 12 A. Probably not in humans. They, 13 again, would probably be allowed to do a 14 dissolution study that showed the same release 15 characteristics. 16 Q. What are you basing that on? 17 A. Basing it on the FDA guidance for 18 bioequivalence testing. 19 Q. Which FDA guidance on 20 bioequivalence testing? 21 A. Probably the one that I referred 22 to in my report. 23 Q. Do you know which year that one 24 is? 25 A. I don't. I know they released a</p>	<p style="text-align: right;">Page 88</p> <p>1 Q. And their reference drug is, 2 again, Exforge HCT? 3 A. Yes. So this is a -- a 4 three-drug combination now. 5 Q. Does Exforge HCT have amlodipine 6 in it? 7 A. Yes. 8 Q. And is Exforge HCT what was also 9 being compared to on the generic valsartan plus 10 HCTZ but not amlodipine? 11 A. Valsartan plus amlodipine alone 12 would be equivalent to the Exforge. Valsartan 13 plus HCTZ would be equivalent to Diovan/HCT. And 14 then valsartan plus amlodipine plus 15 hydrochlorothiazide would be equivalent to the 16 Exforge HCT. 17 Q. Understood. Thank you for that 18 clarification. 19 And so that last paragraph on 20 page 39, you are discussing Teva's ANDA 2004354, 21 valsartan plus amlodipine plus HCTZ, correct? 22 A. Yes. 23 Q. And I don't see that you 24 identified the studies in this ANDA. Do you see 25 if you did, Doctor?</p>
<p style="text-align: right;">Page 87</p> <p>1 new one maybe last year, but I don't think there 2 was substantial changes in it. 3 Q. Did you disagree with anything in 4 the FDA's guidance? 5 MR. FOWLER: Objection, form. 6 THE WITNESS: I'd have to see 7 what you're referring to. 8 BY MR. VAUGHN: 9 Q. As you're sitting here today, do 10 you recall disagreeing with any of the FDA's 11 guidance on bioequivalency studies? 12 A. As I sit here today, I do not 13 recall that. But I don't know what you're 14 referring to. It's -- I -- it's so vague, I 15 can't -- I can't really answer your question. 16 Q. Are you giving any regulatory 17 opinions in this litigation? 18 A. I'm giving no regulatory opinions 19 in this case. I think there are other people that 20 have been asked to provide opinions that are much 21 more qualified than I on that. 22 Q. At the bottom of page 39, we are 23 now in the section regarding valsartan plus 24 amlodipine plus HCTZ, correct? 25 A. Yes.</p>	<p style="text-align: right;">Page 89</p> <p>1 A. I don't see a specific study 2 number. 3 Q. Is there a reason for that? 4 A. It -- it wouldn't have been an 5 oversight on my part, so it must not have been 6 that the actual study number was provided in the 7 materials I was given to review or that I asked 8 for to review. 9 Q. And if the Defendants had that 10 information, you would have expected that they 11 would have given it to you, correct? 12 A. Yes. I'm sure they had it, and 13 it wasn't in the materials that I received. 14 Q. You were sure that the Defense 15 attorneys had it, but they did not give it to you? 16 MR. FOWLER: Objection, form. He 17 didn't say that. 18 THE WITNESS: Yeah, what -- what 19 I meant to -- to mean is that the file 20 that came through Defense lawyers to me 21 from Teva, Teva must not have provided 22 it in what was sent to them to give to 23 me. So I had no direct contact with 24 Teva. 25 BY MR. VAUGHN:</p>

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<p>1 Q. And these studies done in Teva's 2 ANDA 200435, they were conducted in 2009, correct? 3 A. Yes, I did have that information. 4 Q. And do you have an opinion on if 5 Teva's valsartan was contaminated with 6 nitrosamines back in 2009? 7 A. I don't know if it was or not. 8 Q. And therefore, if it was not 9 contaminated with nitrosamines back in 2009, these 10 studies don't tell us anything on if nitrosamines 11 impact the bioequivalency of Teva's valsartan plus 12 amlodipine plus HCTZ, correct? 13 A. Incorrect. Again, this is 14 an -- an even more extreme example of making my 15 point. You now have three drugs in milligram 16 quantities that don't have overlapping mechanisms 17 of metabolism that show no altered bioequivalence. 18 Q. And it's your opinion that that 19 supports that nitrosamines can't alter the 20 bioequivalency of these drugs? 21 A. The absence of an overlapping 22 mechanism of metabolism or distribution, 23 absolutely, I believe that. 24 Q. Did you discuss any other 25 bioequivalency studies in your expert report,</p>	<p>1 I'm even under the impression 2 that some of the Diovan may have had nitrosamines 3 in them as well. Again, I don't think it alters 4 my conclusion at all because it would have no 5 impact on the bioequivalence studies. 6 Q. Did the Defense attorneys tell 7 you to assume that some of the generic valsartan 8 that was studied in these bioequivalency studies 9 were contaminated with nitrosamines? 10 A. Defense attorneys did not tell me 11 to assume anything. They have access to 12 information through other depositions and things 13 that I'm not aware of, but they did tell me that 14 there was the likelihood that some of these 15 generics contained NDMA even before ZHP identified 16 that it had NDMA. 17 Q. How far back did the Defense 18 attorneys tell you that the contamination likely 19 goes? 20 A. I was not given a time frame. I 21 do not know that. 22 Q. And so when you testify -- 23 A. I think it was -- 24 Q. Sorry, go ahead. 25 A. Yeah. I think I was going to say</p>
Page 91	Page 93
<p>1 other than the ones that we have covered? 2 A. I'm assuming you went through 3 every one that -- I haven't going back to -- to do 4 a head count, but I'm assuming it's every one. So 5 I have no additional ones that I had access to. 6 Q. And all of the ones that we 7 reviewed, none of them were you aware if 8 nitrosamines were in the drug product, correct? 9 MR. FOWLER: Asked and answered. 10 THE WITNESS: I don't believe 11 that I -- I don't know, but I'm under 12 the impression that some of them did. 13 BY MR. VAUGHN: 14 Q. Which ones are you under the 15 impression had nitrosamines in them when they were 16 conducting the bioequivalency studies? 17 MR. FOWLER: Objection, asked and 18 answered. 19 THE WITNESS: I -- I don't know 20 which ones, but I'm under the impression 21 that some did. 22 BY MR. VAUGHN: 23 Q. Do the -- 24 A. I'm even under the 25 impression -- I'm sorry.</p>	<p>1 that, again, in -- in reading Dr. Najafi's 2 deposition, I think he was the one that concluded 3 or -- or stated that even Diovan had some NDMA in 4 it. And so I'm saying it doesn't matter. The 5 bioequivalence, and therefore the systemic 6 exposure, and therefore the systemic effect of 7 generic valsartan products are completely 8 independent of whether there is or isn't NDMA in 9 there or whether it was in the branded products or 10 not. 11 Q. Earlier you testified that you 12 were under the impression they had nitrosamines in 13 them when they were [sic] conducted the 14 bioequivalency studies. How are you under that 15 impression? 16 MR. FOWLER: Objection: Form, 17 vague. 18 THE WITNESS: Again, I'm -- I'm 19 under the impression from discussions 20 I've had with counsel that there were 21 some generic manufacturers that have 22 identified that they might have had NDMA 23 even at the time that some of these 24 bioequivalence studies were conducted. 25 BY MR. VAUGHN:</p>

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<p>1 Q. Did you refute --</p> <p>2 A. And it --</p> <p>3 Q. Sorry.</p> <p>4 A. -- doesn't matter. No. I was</p> <p>5 just going to say it doesn't matter, because it's</p> <p>6 not going to have any effect on the bioequivalence</p> <p>7 anyway.</p> <p>8 Q. Did you review any documents that</p> <p>9 indicated that any of the drug products tested in</p> <p>10 these bioequivalency studies were actually</p> <p>11 contaminated with nitrosamines?</p> <p>12 A. I have -- I have seen no such</p> <p>13 documents, no.</p> <p>14 MR. VAUGHN: Why don't we go off</p> <p>15 the record.</p> <p>16 THE VIDEOGRAPHER: The time is</p> <p>17 now 11:53 a.m. We are off the record.</p> <p>18 (Lunch recess observed.)</p> <p>19 THE VIDEOGRAPHER: The time is</p> <p>20 12:38 p.m. We're back on the record.</p> <p>21 BY MR. VAUGHN:</p> <p>22 Q. Welcome back, Dr. Bottorff.</p> <p>23 MR. VAUGHN: Melisha, can we pull</p> <p>24 up the 2011 FDA Guidance for Submission</p> <p>25 of Summary Bioequivalence Data for</p>	<p>1 a citation down to the Final Rule: "Requirements</p> <p>2 for submission of bioequivalence data that was</p> <p>3 published in the Federal Register on January 16th,</p> <p>4 2009," correct?</p> <p>5 A. Correct.</p> <p>6 Q. And do you agree that an ANDA</p> <p>7 applicant should submit all of their</p> <p>8 bioequivalency studies, even studies which failed?</p> <p>9 MR. FOWLER: Objection: Calling</p> <p>10 for a regulatory opinion, outside the</p> <p>11 scope.</p> <p>12 THE WITNESS: I can sit here and</p> <p>13 read that the same as you can, but,</p> <p>14 again, I -- I don't have opinions</p> <p>15 on -- on regulatory issues.</p> <p>16 BY MR. VAUGHN:</p> <p>17 Q. And so you also don't have an</p> <p>18 opinion on if they're supposed to submit failed</p> <p>19 bioequivalency studies that happened after the</p> <p>20 submission of their ANDA?</p> <p>21 MR. FOWLER: Same objection.</p> <p>22 THE WITNESS: Yeah. Again, I</p> <p>23 have no opinion on that.</p> <p>24 MR. VAUGHN: All right. Melisha,</p> <p>25 let's go to the -- the FDA's 2021 Draft</p>
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<p>1 ANDAs?</p> <p>2 And this will be Exhibit 4.</p> <p>3 (Exhibit 4 was marked.)</p> <p>4 BY MR. VAUGHN:</p> <p>5 Q. All right. Have you reviewed</p> <p>6 this document previously, Dr. Bottorff?</p> <p>7 A. Yes, I have.</p> <p>8 MR. VAUGHN: Melisha, can we go</p> <p>9 to PDF page 4? It's page 1 at the</p> <p>10 bottom of the document.</p> <p>11 BY MR. VAUGHN:</p> <p>12 Q. All right. I'm looking at line</p> <p>13 19. Actually, it starts on line 18. Do you see,</p> <p>14 Doctor, where it says: "FDA's final rule on</p> <p>15 requirements for submission of bioequivalence data</p> <p>16 requires an ANDA applicant to submit data from all</p> <p>17 bioequivalence studies the applicant conducts on a</p> <p>18 drug product formulation submitted for approval,</p> <p>19 including studies that do not demonstrate that the</p> <p>20 generic product meets the current bioequivalence</p> <p>21 stamp criteria"?</p> <p>22 A. I see that.</p> <p>23 Q. And at the top of this document,</p> <p>24 it does say that the document contains nonbinding</p> <p>25 recommendations, but the sentence I just read has</p>	<p>1 Guidance now.</p> <p>2 And this will be Exhibit 5.</p> <p>3 (Exhibit 5 was marked.)</p> <p>4 BY MR. VAUGHN:</p> <p>5 Q. Doctor, is this the 2021 Guidance</p> <p>6 that you were referencing earlier in this</p> <p>7 deposition?</p> <p>8 A. Yes. It's the one that I said</p> <p>9 I'd also seen. It existed in a -- in a draft</p> <p>10 format.</p> <p>11 MR. VAUGHN: Go to PDF page 8,</p> <p>12 Melisha. It's going to be page 5 at the</p> <p>13 bottom. And it might be PDF page 9.</p> <p>14 MR. FOWLER: So let me just have</p> <p>15 a running objection to the relevance of</p> <p>16 this 2021 Guidance to this case, so I</p> <p>17 don't interrupt you.</p> <p>18 BY MR. VAUGHN:</p> <p>19 Q. All right. Doctor, on line 147</p> <p>20 where it says: "If a drug product is intended for</p> <p>21 use in both sexes, the applicant should include</p> <p>22 similar proportions of males and females in the</p> <p>23 study or provide a justification supporting the</p> <p>24 use of a single-sex population."</p> <p>25 Why is that?</p>

<p style="text-align: right;">Page 98</p> <p>1 MR. FOWLER: Objection, calls for 2 a regulatory opinion. 3 Go ahead, to the extent you can 4 answer. 5 THE WITNESS: Yeah, I -- I don't 6 know why, but I know it's done. On my 7 CV, I don't know if it was noted or not, 8 but I've been added to a National 9 Investigational Review Board for a 10 company called Advarra. And we review 11 Phase 1 protocols on a weekly basis from 12 a variety of pharmaceutical companies, 13 and I can tell you that the vast 14 majority of them have about an equal 15 number of males and females. 16 Provided, there's all kinds of 17 stipulations about making sure that it's 18 females either of nonchild-bearing 19 potential or who have some of the -- the 20 highest level of -- of pregnancy 21 prevention techniques in place. 22 BY MR. VAUGHN: 23 Q. And designing a bioequivalency 24 study like this with -- using both sexes, is that 25 something that's new as of 2021, or does that date</p>	<p style="text-align: right;">Page 100</p> <p>1 A. I'm not sure. I -- I really 2 don't know. Maybe to broaden the populations of 3 people that get exposed to the early phases of 4 drug development. 5 Q. In a drug like valsartan, it is 6 given to both males and females, correct? 7 A. Well, if the females aren't 8 pregnant. There's a Black Box Warning: Do not 9 give it to pregnant females. 10 Q. And so is that one reason that 11 you'd want to have both sexes in your studies, is 12 so you understand how it works in both males and 13 females? 14 MR. FOWLER: Form. 15 THE WITNESS: Again, I don't know 16 what led to a change, and I don't know 17 when the change occurred. 18 BY MR. VAUGHN: 19 Q. Line 153, it notes: "If a drug 20 product is prom- -- predominantly intended for the 21 use in the elderly, the applicant should include 22 as many subjects as possible at or above age 60." 23 Do you know why that's 24 recommended? 25 A. I'm assuming for what it actually</p>
<p style="text-align: right;">Page 99</p> <p>1 back before 2021? 2 A. I, again, can't tell you when 3 that started, but I know it's being practiced as 4 of today. Since I've been on that IRB, I've seen 5 numerous trials come through that are practicing 6 this standard. 7 Q. And you testified that you've 8 done bioequivalency studies dating all the way 9 back to college, correct? 10 A. Yes. 11 Q. And in those bioequivalency 12 studies, was there a fairly equal number of males 13 and females in the studies? 14 A. There were not. And that was, 15 like, 1982-1983. So it was a fair number of years 16 ago. 17 Q. And do you have any idea when 18 that started to change, that they were 19 recommending to use equal numbers of male and 20 females in the study? 21 MR. FOWLER: Asked and answered. 22 THE WITNESS: I -- I do not. 23 BY MR. VAUGHN: 24 Q. And you do not know why that's 25 recommended?</p>	<p style="text-align: right;">Page 101</p> <p>1 says in that sentence, if it's predominantly 2 intended to be used in the elderly. 3 Q. Do elderly metabolize drugs 4 differently than young people? 5 A. Again, much like the previous 6 question about cirrhosis, it's -- it's not a 7 given. There are many, many studies that I've 8 seen over the years of my career where the 9 pharmacokinetics, and therefore the bioequivalence 10 of a drug, were not altered just by being older. 11 It's more likely the pharmacodynamics that change, 12 sensitivity to the heart rate adjustments 13 or -- it's more the pharmacodynamic end points 14 that change with -- with aging, not so much the 15 pharmacokinetic end point. Sometimes. Sometimes 16 it does. It's not a blanket statement 17 that -- that fits all. 18 Q. So it sometimes does. 19 Would that be a reason you'd want 20 to actually test it in the population the drug is 21 being given to? 22 A. Well, I mean, that's one reason. 23 Q. Can you give me additional 24 reasons? 25 A. Well, maybe, like I said, because</p>

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1 they're sensitive, and so you might want to do
2 studies with lower doses, if you didn't do
3 bioequivalence studies with lower doses before.
4 Q. In your opinion, what's the
5 average age of a valsartan user?
6 MR. FOWLER: Objection: Form
7 speculation.
8 THE WITNESS: I -- I could not
9 even come close to what the right answer
10 would be, but I can tell you when you
11 look at the FDA-approved indications for
12 hypertension, heart failure and
13 postmyocardial infarction, those are not
14 going to be 18-year-olds, 20-year-olds,
15 25-year-olds. They're going to be 50-
16 60-, 70-year-olds.
17 BY MR. VAUGHN:
18 Q. And then looking at line 169, it
19 reads: "In such situations, applicant should
20 attempt to enroll patients for whom the drug is
21 intended to treat and whose disease process and
22 treatments are stable for the duration of the
23 study."
24 Do you see that, Doctor?
25 A. Yes.

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1 Q. Do you agree with that statement?
2 A. Well, not in isolation without
3 the sentence before it. Because in some
4 situations, the drug has a safety consideration
5 that would preclude its use in healthy subjects.
6 So I'm thinking -- what jumps out at me at that
7 point are new cancer drugs.
8 Q. Would --
9 A. You would only want to test those
10 in patients with stable cancer.
11 Q. Thank you for that clarification.
12 Now, when it applies to
13 valsartan, would there be any reason why it should
14 not be tested in the patient population it's
15 intended to treat?
16 MR. FOWLER: Objection: Form,
17 mischaracterizing.
18 THE WITNESS: And I -- I don't
19 think -- again, I think this starts
20 getting into a realm of -- of
21 regulatory, but I don't think the
22 companies who did bioequivalence testing
23 in younger, healthy, normal volunteers
24 was anything other than what the FDA
25 expected to see.

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1 BY MR. VAUGHN:
2 Q. And you see the next line, it
3 says: "Investigational New Drug Application may
4 be required for certain products (such as
5 cytotoxic products.)" And then it cites to 21 CFR
6 312.2(c).
7 Do you see that, Doctor?
8 A. Yes.
9 Q. Were you aware of that?
10 A. Well, I've previously read this,
11 but -- so, yes, I was aware of it.
12 Q. What is an Investigational New
13 Drug Application?
14 A. That's for a drug that's never
15 been given to humans, and so you're looking to get
16 approval to start testing in humans.
17 Q. Is valsartan cytotoxic?
18 A. No.
19 Q. Is NDMA cytotoxic?
20 MR. FOWLER: Form.
21 THE WITNESS: I -- I don't
22 believe so, in what the definition of
23 cytotoxic is, to my recollection. I
24 think of cytotoxic as either antibiotics
25 that are cytotoxic to an organism or

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1 cancer drugs that are cytotoxic to
2 cancer cells.
3 BY MR. VAUGHN:
4 Q. What is your definition of
5 cytotoxicity?
6 A. It's a drug that kills cells.
7 And we're talking here about active ingredient, so
8 it's an active ingredient whose intent for use is
9 cytotoxicity.
10 MR. VAUGHN: All right. If we
11 can go to page 22 at the bottom,
12 Melisha. I'm not sure what PDF page it
13 is.
14 BY MR. VAUGHN:
15 Q. All right. I'm looking at the
16 line 846, Handling of Outliers. Doctor, you see
17 this first sentence says: "Applicant should not
18 remove data from the statistical analysis of
19 bioequivalency studies solely because that data
20 are identified as statistical outliers."
21 Do you agree with that statement?
22 A. Well, yes, it's in the FDA
23 document.
24 Q. And you agree that a manufacturer
25 shouldn't remove statistical outliers even before

<p style="text-align: right;">Page 106</p> <p>1 2021, right?</p> <p>2 A. Again, the way in which the data</p> <p>3 are handled can vary. Some of this is relating to</p> <p>4 the fact that some patients or subjects will later</p> <p>5 to [sic] be found to have some reason for it, and</p> <p>6 some of that could be biologic. I mean, I don't</p> <p>7 know the details behind it. Starts getting into a</p> <p>8 statistical handling of the data.</p> <p>9 That's not really what I -- what</p> <p>10 I've done.</p> <p>11 Q. You have not done a statistical</p> <p>12 handling of the data of any of these</p> <p>13 bioequivalency studies?</p> <p>14 A. The kind that are down below in</p> <p>15 870, I have, but not removal of outliers, I've</p> <p>16 not.</p> <p>17 Q. Did you notice in any of the</p> <p>18 bioequivalency studies that you reviewed that the</p> <p>19 manufacturer removed outliers?</p> <p>20 A. Never saw any reference to that</p> <p>21 at all.</p> <p>22 Q. Then going to line 854, it notes</p> <p>23 that: "Data from redosing studies are not</p> <p>24 considered as evidence to support removal of</p> <p>25 outlier data from the statistical analysis. Note</p>	<p style="text-align: right;">Page 108</p> <p>1 what I had in relation to these document requests,</p> <p>2 and I either provided answers or what was</p> <p>3 requested.</p> <p>4 Q. Approximately how many documents</p> <p>5 did you send to GT in relation to this document</p> <p>6 request?</p> <p>7 MR. FOWLER: Objection: Form,</p> <p>8 vague, time frame.</p> <p>9 THE WITNESS: Well, I mean, if</p> <p>10 you want to go through one-by-one....</p> <p>11 But in No. 1, I did not send invoices</p> <p>12 because they had them already.</p> <p>13 BY MR. VAUGHN:</p> <p>14 Q. Oh, Doctor, I just mean in total,</p> <p>15 if that helps you. Just cuts the time up.</p> <p>16 MR. VAUGHN: What's your</p> <p>17 objection?</p> <p>18 MR. FOWLER: You said -- you mean</p> <p>19 in total. You mean a total of documents</p> <p>20 in re- -- sent in response to all 15</p> <p>21 requests? I don't understand --</p> <p>22 MR. VAUGHN: Yeah, that's exactly</p> <p>23 what I'm asking. Yeah. Out of all the</p> <p>24 documents requested --</p> <p>25 MR. FOWLER: As opposed to</p>
<p style="text-align: right;">Page 107</p> <p>1 that all subject data should be submitted and</p> <p>2 potential outliers flagged with appropriate</p> <p>3 documentation as part of the submission."</p> <p>4 And you agree with that as well,</p> <p>5 correct, Doctor?</p> <p>6 A. Yes, it's -- it's in their</p> <p>7 document.</p> <p>8 MR. VAUGHN: Let's pull up the</p> <p>9 depo notice, Melisha.</p> <p>10 It's going to be Exhibit 6.</p> <p>11 (Exhibit 6 was marked.)</p> <p>12 BY MR. VAUGHN:</p> <p>13 Q. Have you seen this document</p> <p>14 before, Dr. Bottorff?</p> <p>15 A. Yes, I have seen it.</p> <p>16 Q. When was this document given to</p> <p>17 you?</p> <p>18 A. I believe it was forwarded the</p> <p>19 day -- well, I don't know in relation to when it</p> <p>20 was received by -- by GT, but I received it in an</p> <p>21 e-mail probably earlier this week.</p> <p>22 Q. And did you help GT in responding</p> <p>23 to this document request?</p> <p>24 A. We went through it line-by-line</p> <p>25 or -- or paragraph-by-paragraph, and I was asked</p>	<p style="text-align: right;">Page 109</p> <p>1 counting?</p> <p>2 MR. VAUGHN: -- in this document,</p> <p>3 I asked him approximately, how many he</p> <p>4 sent to GT.</p> <p>5 THE WITNESS: I'm running down to</p> <p>6 see. I have my recollection in my head,</p> <p>7 but I wanted to look at each of the</p> <p>8 points to make sure that I didn't miss</p> <p>9 something. But the only thing that I</p> <p>10 had that I could give were the notes</p> <p>11 that I was under the impression were</p> <p>12 sent to you.</p> <p>13 I had no PowerPoints. I had no</p> <p>14 tables and charts. I had no books. Any</p> <p>15 of the other things that were requested</p> <p>16 here, I didn't have any- -- anything to</p> <p>17 provide.</p> <p>18 BY MR. VAUGHN:</p> <p>19 Q. Your notes were produced to us.</p> <p>20 I do appreciate you getting those to the Defense</p> <p>21 attorneys. And it was both the notes for the</p> <p>22 general causation expert report you did and the</p> <p>23 class action expert report you did.</p> <p>24 Had you previously given GT's</p> <p>25 Defense attorneys your notes for the general</p>

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1 causation expert report?
2 A. Yes, I had.
3 Q. And when was that?
4 A. I'm assuming in response to the
5 exact same kind of document prior to the
6 deposition for -- for the general causation.
7 MR. FOWLER: They were provided
8 to you at the time of the general
9 causation deposition, Mr. Vaughn.
10 MR. VAUGHN: Did I say they
11 weren't?
12 MR. FOWLER: Your question
13 suggested otherwise, but I just want to
14 be clear on this record.
15 BY MR. VAUGHN:
16 Q. Doctor, are you aware that the
17 Defense produced 16,632 documents 48 hours ago for
18 your reliance materials?
19 A. No. The -- when you combine my
20 reliance materials from the first phase of
21 litigation to this phase, there's a lot of -- a
22 lot of articles that have been looked at and read
23 and a lot of multipage documents, like the
24 Guidance for Industry that we looked at a while
25 ago. So did I do a head count of those? No, I

Page 111

1 didn't.
2 Q. And I'm not talking about pages.
3 I mean documents. They produced 16,632 documents.
4 You think you have reviewed somewhere close to
5 16,000 documents in relation to this litigation?
6 A. Whatever was sent to you were
7 things that I reviewed. Some in more detail than
8 others.
9 Q. And how was that determined that
10 you had reviewed those documents?
11 MR. FOWLER: Form.
12 I don't understand the question.
13 THE WITNESS: I'm not sure I do
14 either, other than if they were
15 documents that -- that I told attorneys
16 that I had looked at or sent to them in
17 a PDF form, along with I read
18 depositions of -- of Plaintiffs'
19 and -- and Defense experts. I read
20 reports from Plaintiff and -- and
21 Defense experts. I'm not sure what to
22 tell you other than we didn't just, you
23 know, randomly select things and throw
24 them on there just to make a number look
25 unbelievable.

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1 BY MR. VAUGHN:
2 Q. And 16,632 sounds kind of
3 unbelievable, doesn't it?
4 MR. FOWLER: Form.
5 THE WITNESS: Not to me, if
6 that's what's on there. I didn't count
7 them.
8 BY MR. VAUGHN:
9 Q. And so you believe that you've
10 identified or sent 16,000 documents to the Defense
11 attorneys?
12 MR. FOWLER: Mischaracterizing.
13 THE WITNESS: Again, what got
14 sent to you, I have a copy of. I
15 haven't counted the files. I mean, I
16 don't -- I don't know.
17 MR. VAUGHN: Melisha, let's pull
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]
25 [REDACTED]

Page 113

1 All right. Doctor, have you ever
2 seen this document before?
3 A. Can you scroll down, please?
4 Q. Yeah. And you can also download
5 it if you would like to review the entire
6 document, Dr. Bottorff.
7 A. I'm sorry. They're -- they're
8 printing it.
9 Q. Okay. Let's go ahead and go off
10 the record, and you just let us know when you're
11 finished reviewing it.
12 MR. FOWLER: Please, no.
13 It -- it's right here. It's right here.
14 We don't need to go off the record.
15 MR. VAUGHN: Oh, okay. I thought
16 you might want time to review it.
17 MR. FOWLER: He'll still need
18 time to review the document. It's eight
19 pages, just looking through it, to
20 answer your question.
21 THE WITNESS: I'm looking for a
22 date.
23 BY MR. VAUGHN:
24 Q. I can let you know that there is
25 no date on this document, but the metadata

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1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 BY MR. VAUGHN:
18 Q. So, Doctor, if a bioequivalency
19 study is -- if the manufacturer is deleting the
20 failed test results and retesting the samples
21 until it achieves the results it sought, would you
22 consider those bioequivalence studies to be
23 legitimate?
24 MR. FOWLER: Objection, form.
25 THE WITNESS: Again, this

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1 is -- this is all regulatory. I have no
2 opinion on the regulatory.
3 BY MR. VAUGHN:
4 Q. Did you not evaluate the
5 legitimacy of the bioequivalency studies that you
6 opined on?
7 A. Yes, and they had approved ANDAs.
8 So they're in a different ball park than what this
9 is.
10 Q. Did you evaluate the underlying
11 studies of the bioequivalency studies to see if
12 any -- scratch that.
13 Did you evaluate the underlying
14 data of the bioequivalency studies to see if
15 failed testing was deleted and retested until it
16 got an accurate result and then submitted the
17 accurate results to the FDA?
18 A. Again, as I testified this
19 morning, I only saw one instance of what was a
20 failed test result, and it was included. My only
21 exposure to that was what I testified to this
22 morning.
23 Q. So you've seen one failed test
24 result. Have you seen any indication of companies
25 retesting samples until they get a different

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1 result?
2 A. Other than what you just handed
3 me, no.
4 Q. And if the companies in this
5 litigation were doing that with their
6 bioequivalency studies, would you consider those
7 studies to be illegitimate?
8 MR. FOWLER: Objection: Form,
9 outside the scope.
10 THE WITNESS: Again, that's a
11 regulatory, and -- and I have no
12 evidence that that occurred or didn't
13 occur, either way.
14 BY MR. VAUGHN:
15 Q. Not from a regulatory side, from
16 a just statistics side from when it comes to a
17 bioequivalency study and the legitimacy of it. Do
18 you consider a bioequivalency study legitimate if
19 they retested the samples until they got the
20 desired results?
21 MR. FOWLER: Objection: Form,
22 scope, incomplete hypothetical.
23 THE WITNESS: Again, the one
24 instance that I saw, there was a failed
25 bioavailability study. They

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1 reformulated and passed, and I saw both
2 examples. There was no attempt -- you
3 know, no sixth time or ten-time attempt
4 or multiple attempts. It was a one-time
5 reformulation, and it led to an approved
6 ANDA.
7 MR. VAUGHN: Let's go to page 5,
8 Melisha.
9 BY MR. VAUGHN:
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]
25 [REDACTED]

Page 126

[REDACTED]

Page 128

[REDACTED]

Page 127

[REDACTED]

Page 129

[REDACTED]

14 Q. All right.

[REDACTED]

Page 130

[REDACTED]

Page 132

[REDACTED]

Page 131

[REDACTED]

Page 133

[REDACTED]

Page 134

[REDACTED]

Page 136

[REDACTED]

Page 135

[REDACTED]

Page 137

[REDACTED]

Page 140

[illegible]

Page 141

[illegible]

Page 142

[REDACTED]

Page 144

[REDACTED]

Page 143

[REDACTED]

Page 145

[REDACTED]

Page 146

[REDACTED]

Page 148

[REDACTED]

Page 147

[REDACTED]

Page 149

[REDACTED]

Page 150

[REDACTED]

Page 152

[REDACTED]

Page 151

[REDACTED]

Page 153

[REDACTED]

Page 154

[REDACTED]

Page 156

[REDACTED]

Page 155

[REDACTED]

Page 157

[REDACTED]

23 Q. All right.

[REDACTED]

Page 158

[REDACTED]

Page 160

[REDACTED]

Page 159

[REDACTED]

Page 161

[REDACTED]

Page 162

[REDACTED]

Page 164

[REDACTED]

Page 163

[REDACTED]

Page 165

[REDACTED]

4 MR. VAUGHN: Let's go to RO-MDL-

5 2875-0026534.

[REDACTED]

Page 166

[REDACTED]

Page 168

[REDACTED]

Page 167

[REDACTED]

Page 169

[REDACTED]

Page 170

[REDACTED]

Page 172

[REDACTED]

Page 171

[REDACTED]

Page 173

[REDACTED]

Page 174

[REDACTED]

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1 This will be Exhibit 19.
2 (Exhibit 19 was marked.)
3 MR. VAUGHN: And if we can scroll
4 down a little bit -- it's about
5 two-thirds of the way down.
6 BY MR. VAUGHN:
7 Q. Doctor, do you see where it says:
8 The pieces of the company, left after bankruptcy,
9 did business as PRACS and returned to the name and
10 the home of one of the legacy companies that had
11 formed Cetero, C-e-t-e-r-o.
12 Have you ever heard of Cetero
13 before?
14 A. I'm not sure.
15 Q. If I represent to you that Cetero
16 is who acquired PRACS, do you have any reason to
17 disagree with that?
18 A. No I have no reason to disagree
19 with that. Like I said, I thought they were
20 bought out or relocated or something. But that's
21 about all I knew.
22 MR. FOWLER: Let me object to
23 relevance of this document and line of
24 questioning.
25 MR. VAUGHN: I'll make it

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[REDACTED]

Page 177

1 relevant real quick for you.
2 Let's go to the FD- -- the FDA
3 letter to Cetero Research, Melisha.
4 This will be Exhibit 20.
5 (Exhibit 20 was marked.)
6 BY MR. VAUGHN:
7 Q. All right. Doctor, you see this
8 is a letter from the FDA to Cetero Research?
9 A. I see that.
10 MR. FOWLER: I'm going to object
11 to the document and any hearsay
12 contained in the document.
13 BY MR. VAUGHN:
14 Q. Have you ever seen this document
15 before, Doctor?
16 A. No.
17 Q. All right. That first paragraph
18 towards the bottom, do you see where it says: FDA
19 investigators have identified significant
20 violations of the bioavailability and
21 bioequivalence requirements of Title 21 Code of
22 Federal Regulations Part 320?
23 A. I see that.
24 Q. Do you see where the FDA goes on
25 to say that these violations include widespread

<p style="text-align: right;">Page 178</p> <p>1 falsification of dates and times in laboratory 2 records and subject sample extractions and the 3 apparent manipulation of equilibrium samples to 4 meet predetermined accepted criteria? 5 MR. FOWLER: Objection: Hearsay, 6 relevance to anything we're talking 7 about here. 8 THE WITNESS: Yeah, I see that. 9 MR. VAUGHN: All right. Let's go 10 to the next page, Melisha. All right. 11 Second paragraph, the last sentence. 12 BY MR. VAUGHN: 13 Q. Do you see where the FDA says: 14 "The Complainant was aware that many of the 15 chemists were manipulating and falsifying data 16 associated with the samples being used within 17 various projects"? 18 MR. FOWLER: Hearsay. A double 19 layer of hearsay. 20 THE WITNESS: I see that. 21 MR. VAUGHN: Let's go to page 5, 22 Melisha. 23 BY MR. VAUGHN: 24 Q. All right. That first paragraph 25 under No. 2, do you see where they are -- the FDA</p>	<p style="text-align: right;">Page 180</p> <p>1 the bottom. 2 BY MR. VAUGHN: 3 Q. Do you see where the FDA says 4 that this calls into question the validity of all 5 of the information documented on your AP sheets 6 including study results that were used as a basis 7 for NDAs and ANDAs submitted to the FDA? 8 MR. FOWLER: Form, relevance, 9 hearsay. 10 THE WITNESS: I mean, yes, I see 11 that. 12 MR. VAUGHN: And let's go to the 13 next page, Melisha. 14 BY MR. VAUGHN: 15 Q. And under the heading 16 Manipulation of Samples, do you see where it says: 17 "FDA has determined that your firm manipulated 18 test samples in order to meet predetermined 19 acceptance criteria"? 20 MR. FOWLER: Form, lack of 21 foundation, facts not in evidence, 22 relevance. 23 THE WITNESS: I see that. 24 MR. VAUGHN: And let's go to 25 page 10, Melisha.</p>
<p style="text-align: right;">Page 179</p> <p>1 notes that there were frequent alterations in 2 laboratory records that occurred over a four-year 3 period from April 1st, 2005 through June 15th, 4 2009? 5 MR. FOWLER: Objection: Facts 6 not in evidence, hearsay. 7 THE WITNESS: I see it. 8 BY MR. VAUGHN: 9 Q. And do you recall the previous 10 bioequivalency studies that we looked at from 11 Mylan were within this date range? 12 A. They were within that date range. 13 Q. And the company conducting their 14 bioequivalency studies is the company that the FDA 15 is saying has frequent alterations in their 16 laboratory records? 17 MR. FOWLER: Objection: Form, 18 hearsay, facts not in evidence. 19 THE WITNESS: Yeah, I don't see 20 which studies it applies to, but I see 21 that. 22 BY MR. VAUGHN: 23 Q. All right. 24 MR. VAUGHN: Let's go down to the 25 fourth paragraph, three lines up from</p>	<p style="text-align: right;">Page 181</p> <p>1 BY MR. VAUGHN: 2 Q. And do you see where the FDA, on 3 the second paragraph, notes they have significant 4 concerns of all data relevant to FDA-regulated 5 research? 6 A. At the Houston facility, yes. 7 Q. And -- 8 A. My recollection is we talked 9 about Minneapolis and North Dakota, not Houston. 10 Q. So it's your opinion that just 11 the Houston office was manipulating data for this 12 company? 13 MR. FOWLER: Objection: Form, 14 mischaracterizing, lack of foundation, 15 facts not in evidence. 16 THE WITNESS: It's not my 17 testimony. It's what's in the letter 18 that you just provided me. 19 MR. VAUGHN: And let's go to 20 page 11, Melisha. 21 BY MR. VAUGHN: 22 Q. And this was signed by the FDA's 23 Chief of Bioequivalence Investigations branch, 24 correct? 25 A. Well, I don't see a signature,</p>

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1 but....

2 Q. The name and the position of the

3 person at the end of the letter is the FDA's Chief

4 of Bioequivalence Investigations branch, correct?

5 MR. FOWLER: Object to the

6 mischaracterization of that being a

7 signature.

8 MR. VAUGHN: Oh, you're right.

9 BY MR. VAUGHN:

10 Q. Signature is the Office of

11 Scientific Investigations and Office of Compliance

12 for the Centers of Drug Evaluation and Research,

13 U.S. FDA, Food & Drug Administration, correct?

14 A. Yes, I see the -- the listing of

15 those people's names and their positions there.

16 MR. VAUGHN: All right, Melisha,

17 let's go to Teva ANDAs Withdrawn over

18 Cetero Data document. Let's go to the

19 second page.

20 This will be Exhibit 21.

21 (Exhibit 21 was marked.)

22 BY MR. VAUGHN:

23 Q. That top paragraph, Doctor, do

24 you see where it says: After a six-year effort,

25 the U.S. FDA has run out of patience with Watson

Page 183

1 Laboratories and InvaGen Pharmaceuticals and is

2 moving to withdraw approval of two of their pr- --

3 abbreviated new drug applications because the

4 firms failed to conduct additional bioequivalency

5 studies for the products the companies' ANDAs were

6 supported by, bioequivalence studies conducted at

7 Cetero Research?

8 MR. FOWLER: Objection: Hearsay,

9 lack of foundation, facts not in

10 evidence, relevance.

11 THE WITNESS: I see that.

12 BY MR. VAUGHN:

13 Q. Are you aware that Watson is now

14 Teva?

15 A. I'm aware that -- now how

16 to -- how to -- how to word who's what, but I

17 think they either bought Watson or incorporated

18 Watson or something.

19 Which -- which ANDAs were

20 withdrawn? Were they the ones I'm talking about

21 or other ANDAs?

22 Q. They're ANDAs that used the same

23 contract research organization to do their

24 bioequivalency studies.

25 A. Well, again, the -- the data that

Page 184

1 you showed me was concerned about the Houston

2 facility. The ANDAs that I cited were done in

3 North Dakota and Minneapolis, No. 1; and then

4 secondly, it looks like the ANDAs that were

5 withdrawn were not the ones that I reported in --

6 in my report.

7 So I think if the FDA had had a

8 problem with those in those other facilities, then

9 they would have withdrawn those like they did

10 these.

11 Q. And you see here it took the FDA

12 six years before they withdrew it, correct?

13 MR. FOWLER: Form.

14 THE WITNESS: I -- I mean,

15 whatever it says, that's what it says,

16 but I'm saying it didn't involve the

17 ANDAs that I reported on.

18 BY MR. VAUGHN:

19 Q. But it did involve the contract

20 research organization that did the studies for the

21 ANDAs you reported on, correct?

22 A. Correct. Except not in the

23 facility that was cited. In the other facilities

24 that was not cited.

25 Q. My headset just made a noise that

Page 185

1 it's low on batteries.

2 MR. VAUGHN: Can we go off the

3 record real quick, just take a

4 five-minute break?

5 THE VIDEOGRAPHER: The time is

6 now 2:45 p.m. We're off the record.

7 (Brief recess observed.)

8 THE VIDEOGRAPHER: The time is

9 2:53 p.m. We're back on the record.

10 MR. VAUGHN: All right, Melisha,

11 can we now pull up

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 [REDACTED]

20 [REDACTED]

21 [REDACTED]

22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

25 [REDACTED]

Page 186

[REDACTED]

Page 188

[REDACTED]

Page 187

[REDACTED]

Page 189

[REDACTED]

Page 190

[REDACTED]

Page 192

[REDACTED]

Page 191

[REDACTED]

14 Q. Okay. All right.

[REDACTED]

Page 193

[REDACTED]

Page 196

[illegible]

Page 197

Page 197

Page 198

[REDACTED]

Page 200

[REDACTED]

Page 199

[REDACTED]

15 Q. Thank you, Doctor.

[REDACTED]

Page 201

[REDACTED]

Page 202

[REDACTED]

Page 204

[REDACTED]

Page 203

[REDACTED]

Page 205

[REDACTED]

Page 206

[REDACTED]

Page 208

[REDACTED]

Page 207

[REDACTED]

Page 209

[REDACTED]

Page 210

[REDACTED]

Page 212

[REDACTED]

Page 211

[REDACTED]

Page 213

[REDACTED]

Page 214

[REDACTED]

Page 216

[REDACTED]

Page 215

[REDACTED]

Page 217

[REDACTED]

16 MR. VAUGHN: All right, Melisha,
17 let's go to EMA Press Release regarding
18 GVK Biosciences.
19 This will be Exhibit 31.
20 (Exhibit 31 was marked.)
21 MR. FOWLER: Let me just lodge an
22 objection to the EMA exhibit having
23 nothing to do with products sold in the
24 U.S.; relevance and hearsay.
25 Go ahead.

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1 BY MR. VAUGHN:
2 Q. Doctor, have you ever seen this
3 May 22nd, 2015 notice by the EMA?
4 A. No.
5 Q. Do you see where the EMA is
6 suspending medications over flawed studies done by
7 GVK Biosciences in India?
8 A. I do see that. I -- I also see
9 later: "There's no evidence of harm or lack of
10 effectiveness of any of the medicines linked to
11 studies conducted by GVK."
12 Q. Were nitrosamines impurities in
13 valsartan known in 2015?
14 A. I don't know.
15 Q. The third paragraph, do you see
16 where EMA is discussing that GVK Biosciences
17 manipulated data regarding generic medications
18 over a period of the last five years?
19 MR. FOWLER: Objection to form,
20 hearsay, lack of foundation, facts not
21 in evidence.
22 THE WITNESS: Which page are we
23 on?
24 BY MR. VAUGHN:
25 Q. On the first page, third

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1 paragraph.
2 A. Three? Yeah, I see that.
3 Q. And the EMA then goes on to say:
4 "Their systemic nature and extended period of time
5 during which they took place and the number of
6 members of staff involved cast doubt on the
7 integrity of the conduct of trials at the site
8 generally, and on the reliability of data
9 generated."
10 Did I read that correctly,
11 Doctor?
12 MR. FOWLER: Objection: Hearsay,
13 lack of foundation, facts not in
14 evidence, and relevance to medicines not
15 sold in the U.S.
16 BY MR. VAUGHN:
17 Q. Now, Doctor, GVK Biosciences in
18 India was doing bioequivalency studies for these
19 companies that were selling in the U.S., correct?
20 MR. FOWLER: Objection: Form,
21 foundation, facts not in evidence.
22 THE WITNESS: Yes, we did see
23 that in some previous documentation that
24 -- that we reviewed.
25 BY MR. VAUGHN:

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1 Q. And GVK Biosciences was doing
2 those bioequivalency tests for Defendants in this
3 litigation over the time period referenced in this
4 letter, correct? Over the last five years, as of
5 2015, e-mails; so between 2010 and 2015, correct?
6 MR. FOWLER: Objection: Form,
7 foundation.
8 THE WITNESS: Yes. But, again,
9 you know, they go on to say: "There's
10 no evidence of harm or lack of
11 effectiveness, and patients should
12 continue to take their medicines as
13 prescribed."
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
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Page 225

[illegible]

Page 226

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Page 228

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18 [REDACTED]
19 [REDACTED]
20 MR. VAUGHN: All right. Melisha,
21 let's pull up Bottorff 0001.
22 This will be Exhibit 33 [sic].
23 (Exhibit 34 was marked.)
24 THE VIDEOGRAPHER: 34, Counsel.
25 MR. VAUGHN: 34, thank you.

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1 BY MR. VAUGHN:
2 Q. Doctor, are the -- these the
3 notes you took in preparation for your general
4 causation expert report?
5 A. Yes.
6 MR. VAUGHN: Melisha, can we go
7 to 11? All right, C? Do you see where
8 that's at, Melisha? Yeah, paragraph.
9 BY MR. VAUGHN:
10 Q. Doctor, what does the last
11 sentence of your notes say on that paragraph?
12 A. "New active ingredient does not
13 equate to an int- -- contaminant." This is not my
14 statement. These are -- in this section of my
15 report, I was making notes on what was in the
16 original filing. So it's a regurgitation of what
17 someone else who filed the -- the causation
18 lawsuit. This isn't me making a statement. It's
19 me regurgitating what was put by someone else in
20 the original lawsuit filed.
21 I even cite page 124, I think, in
22 that paragraph just above. In the same paragraph,
23 but just above there. So this isn't me. This is
24 me quoting what was in the document I reviewed.
25 Q. Okay. And what about further

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1 down right below the very bottom where you note:
2 "FDA inactive ingredients database does not
3 involve contaminants which are covered under
4 chemical hazards," is that from a complaint?
5 A. At this point, to put it into
6 context, I was talking about the FDA definition of
7 inactive versus an active ingredient, like I was
8 referring to a few minutes ago, where the active
9 ingredient is a drug product intended to furnish a
10 pharmacologic activity in the diagnosis, cure,
11 medication, treatment or prevention of disease.
12 Then there is an inactive
13 ingredient database. And the FDA's inactive
14 ingredient database are for things like
15 excipients, methyl cellulose, mannitol, you know,
16 things that are used in the tableting process. So
17 that inactive ingredient database does not include
18 contaminants. That's under Chemical Hazards in
19 their database.
20 Q. And why are you taking notes on
21 contaminants?
22 A. Because the section of the report
23 or the original suit that was filed kept calling
24 the -- the valsartan products unapproved because
25 of the president [sic] -- presence of a

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1 contaminant. So I was making notes about what the
2 FDA's definitions are in response to that portion
3 of the filing.
4 Q. Is NDMA or NDEA chemical hazards?
5 A. I don't know if they're under the
6 Chemical Database or not, but they're clearly
7 considered an impurity.
8 Q. Are NDMA and NDEA chemicals?
9 A. Chemicals.
10 Q. What does the word "hazardous"
11 mean to you?
12 A. Causing hazard.
13 Q. What does "hazard" mean to you?
14 A. Some form of hazard. It's a very
15 broad definition.
16 Q. So it's your position -- go
17 ahead.
18 A. I'm sorry. Just in my reports, I
19 never disagreed with the IARC definition of NDMA,
20 or NDEA for that matter, being a probable human
21 carcinogen, which is exactly the category that
22 they're listed in. I've never disagreed with that
23 at all. What I've always contended in both
24 reports, that it's an issue of how much and in
25 what form of intake.

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1 Q. You don't disagree with the IARC
2 definition that NDMA or NDEA are probable human
3 carcinogens, but you dropped it from the second
4 version of your expert report?
5 A. I dropped --
6 Q. Is it --
7 A. -- saying that I don't believe --
8 that I don't believe they are able to cause human
9 carcinogenesis in the route of administration and
10 at the doses or exposure levels that we're talking
11 about.
12 Q. Is it -- in your opinion about
13 the drugs -- that when drugs are approved but that
14 they are contaminated -- scratch that.
15 Is it your position that a drug
16 is only contaminated when it reaches an unsafe
17 level of impurity or contaminant?
18 MR. FOWLER: Objection to form.
19 You're outside the scope of the class
20 certification report, Counsel. I'm
21 letting this go a little bit, but you're
22 -- you're far afield.
23 You need the question again,
24 Doctor?
25 THE WITNESS: Yeah, if I'm

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1 expected to answer it, I would like to
2 hear the question again.
3 MR. VAUGHN: Court Reporter?
4 THE COURT REPORTER: Yes?
5 MR. VAUGHN: I can reask it.
6 THE COURT REPORTER: It's okay.
7 I can --
8 MR. FOWLER: We'll hear -- we'll
9 hear it from the court reporter, please.
10 Go ahead.
11 THE COURT REPORTER: Okay.
12 (The previous question was read
13 into the record as follows: "You don't
14 disagree with the IARC definition that
15 NDMA or NDEA are probable human
16 carcinogens, but you dropped it from the
17 second version of your expert report?")
18 THE WITNESS: And so, no, there
19 was no intent by, quote/unquote,
20 dropping it from my second report, which
21 was implying that it was done
22 intentionally, which it was not. So I
23 still agree with the IARC classification
24 of being probable human carcinogens. I
25 have -- I have no reason to disagree

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1 with that.
2 My point is in humans, I don't
3 believe they're carcinogenic in the
4 manner in which they are taken, which is
5 oral, at the levels of exposure, which
6 are in the low microgram quantities.
7 BY MR. VAUGHN:
8 Q. And is it your position, then,
9 that the contamination has to reach an unsafe
10 level before it's actually considered a
11 contamination?
12 MR. FOWLER: Objection, beyond
13 the scope of this report, Counsel.
14 Can you make any proffer how that
15 possibly relates to the class
16 certification report that he has filed,
17 or am I just missing something?
18 BY MR. VAUGHN:
19 Q. Doctor, do you think these drugs
20 have any value?
21 A. What I believe, which is in the
22 -- the rather lengthy Bioequivalence section of my
23 report, is that the bioequivalence, due to the
24 presence of NDEA or NDMA, is not altered and,
25 therefore, they produce the intended therapeutic

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1 benefit, whether it was lowering blood pressure or
2 managing heart failure or in a post-MI situation.
3 So, no, I don't believe they had
4 any loss of their therapeutic benefit.
5 Q. Are you aware of it being illegal
6 to sell a drug with an unsafe level of
7 nitrosamines in them?
8 MR. FOWLER: Objection to form.
9 By the very question, it called for a
10 legal conclusion.
11 MR. VAUGHN: Please quit
12 interrupting. You're -- you're coaching
13 him. You've been coaching him the
14 entire deposition.
15 MR. FOWLER: No, I'm not.
16 MR. VAUGHN: These are improper
17 depositions. We're going to reserve our
18 right for sanctions.
19 MR. FOWLER: So the Court has
20 asked for specificity in objections,
21 which I've provided, and it's a proper
22 objection. Asking him if something is
23 illegal asks for a legal conclusion.
24 MR. VAUGHN: Do you not recall
25 the Court sanctioning you guys because

<p>Page 238</p> <p>1 you were objecting to "the document 2 speaks for itself" previously, which has 3 been one of your objections in this 4 deposition? Do you recall that, 5 Counselor? 6 MR. FOWLER: I'm not testifying, 7 Counsel. Move on. 8 BY MR. VAUGHN: 9 Q. Doctor, are you aware that it 10 would be illegal to sell a drug with unsafe levels 11 of nitrosamines in them in the United States? 12 MR. FOWLER: Objection, form. 13 THE WITNESS: And -- and my 14 answer is no, I do not have any opinion 15 on what becomes legal or illegal. I 16 have no legal opinions in this case. 17 BY MR. VAUGHN: 18 Q. If it would be illegal to sell 19 something in the United States, does it really 20 have any value? 21 MR. FOWLER: Form. 22 THE WITNESS: Again, I have no 23 opinions on legality. My opinions were 24 on whether the bioequivalence was 25 violated by the presence of the</p>	<p>Page 240</p> <p>1 training and background, but my 2 understanding of adulteration are 3 impurities that are outside the 4 manufacturing process, so during storage 5 or some other nonmanufacturing process 6 that results in adulteration. 7 BY MR. VAUGHN: 8 Q. Transportation of the drug 9 product count, if it got contaminated during 10 transportation? 11 A. I think that probably would fit 12 under that adulterated category, because it's not 13 part of the manufacturing process. 14 Q. And do you know if any of the 15 Defendants are claiming that their product got 16 contaminated during transportation? 17 A. Never seen such materials or 18 documentation. 19 Q. Are you aware that if a drug is 20 contaminated, it's considered adulterated? 21 MR. FOWLER: You're asking for a 22 regulatory opinion. It's outside the 23 scope of this report. 24 THE WITNESS: Yeah. Again, I -- 25 I don't have regulatory input. That's</p>
<p>Page 239</p> <p>1 impurities, and I do not believe that 2 and I believe they maintain their 3 therapeutic expected response. 4 BY MR. VAUGHN: 5 Q. Based purely off of 6 bioequivalency studies that you reviewed that did 7 not involve nitrosamines in the drug product? 8 A. I believe in answering that 9 question a few times before, I said that there's a 10 likelihood that some of the products did have 11 nitrosamine in them. And if they did, it still 12 wouldn't have affected their bioequivalence, and 13 therefore their therapeutic response. 14 Q. And you have no document to cite 15 to that they were likely contaminated at that 16 time? 17 A. I have no document. I've -- I've 18 previously stated that. 19 Q. Do you have an understanding of 20 what it means for a drug to be adulterated? 21 MR. FOWLER: Objection: Form, 22 outside the scope of this general -- 23 this class action report. 24 THE WITNESS: I have a -- a basic 25 understanding because of my pharmacy</p>	<p>Page 241</p> <p>1 -- that's not the nature of my report. 2 BY MR. VAUGHN: 3 Q. As a pharmacist, do you have an 4 understanding that an adulterated drug is not 5 supposed to be sold to U.S. consumers? 6 MR. FOWLER: Objection to form. 7 Again, outside the scope of the class 8 cert report and opinions therein. 9 THE WITNESS: Again, 10 adulteration, I don't know is what we're 11 talking about here, but pharmacists 12 would not dispense a known adulterated 13 product. 14 BY MR. VAUGHN: 15 Q. I have no further questions at 16 this time. 17 MR. FOWLER: We'll take a few 18 minutes, and I've got some redirect. 19 Let's take ten. 20 THE VIDEOGRAPHER: The time is 21 now 4:13 p.m. We're off the record. 22 (Brief recess observed.) 23 THE VIDEOGRAPHER: The time is 24 4:26 p.m. We're back on the record. 25 EXAMINATION</p>

<p style="text-align: right;">Page 242</p> <p>1 BY MR. FOWLER:</p> <p>2 Q. Dr. Bottorff, I'd like to show</p> <p>3 you what I'm marking as Bottorff Exhibit 35. And</p> <p>4 -- which is Defendants' Responses and Objections</p> <p>5 to Plaintiffs' Notice of Videotaped Oral</p> <p>6 Deposition Michael Bottorff, Pharm.D.</p> <p>7 (Exhibit 35 was marked.)</p> <p>8 BY MR. FOWLER:</p> <p>9 Q. Handing you that. Have you seen</p> <p>10 that document before?</p> <p>11 A. Yes.</p> <p>12 Q. You've reviewed that with us?</p> <p>13 A. I did.</p> <p>14 Q. Okay. Let me mark as Exhibit 36</p> <p>15 your Curriculum Vitae, Doctor.</p> <p>16 (Exhibit 36 was marked.)</p> <p>17 BY MR. FOWLER:</p> <p>18 Q. Can you tell us whether that is</p> <p>19 your -- your current CV?</p> <p>20 A. Yes.</p> <p>21 MR. VAUGHN: Real quick, Counsel.</p> <p>22 Are these in the -- the folder for me to</p> <p>23 access?</p> <p>24 MR. FOWLER: I believe so.</p> <p>25 (Discussion off the record.)</p>	<p style="text-align: right;">Page 244</p> <p>1 CV. So it went -- it went beyond just me being</p> <p>2 involved in some bioequivalence studies in around</p> <p>3 1982 or 1983, but probably the next ten years, I</p> <p>4 did maybe a dozen more of those kinds of studies.</p> <p>5 Q. Doctor, do you recall some</p> <p>6 questions towards the end of -- of the questioning</p> <p>7 today with -- where you mentioned definitions of</p> <p>8 FDA concerning active ingredients and inactive</p> <p>9 ingredients.</p> <p>10 Do you recall those questions?</p> <p>11 A. I do.</p> <p>12 Q. Let me mark Exhibit 37. This is</p> <p>13 21 CFR 314.3 Definitions.</p> <p>14 (Exhibit 37 was marked.)</p> <p>15 BY MR. FOWLER:</p> <p>16 Q. And if you'd take a look at that,</p> <p>17 Doctor, and I'd ask you: Does that document</p> <p>18 contain FDA's definitions of those active</p> <p>19 ingredient, inactive, things like that?</p> <p>20 A. Yeah. This has -- I mean, it's</p> <p>21 the -- it's the Code of Federal Regulations 314,</p> <p>22 so they're in here.</p> <p>23 Q. Can you locate the Active</p> <p>24 Ingredient definition and read it for the record,</p> <p>25 please?</p>
<p style="text-align: right;">Page 243</p> <p>1 MR. FOWLER: Oh, I see what he's</p> <p>2 doing. Sorry, Counsel. I didn't</p> <p>3 understand my -- my colleague. He's --</p> <p>4 he's load- -- loading those up.</p> <p>5 BY MR. FOWLER:</p> <p>6 Q. Is that -- continuing on 36,</p> <p>7 Doctor.</p> <p>8 Does that CV include your more</p> <p>9 recent appointment to what you referred to as the</p> <p>10 IRB?</p> <p>11 A. Yeah, the Advarra IRB is on here.</p> <p>12 Q. Doctor, you were asked early on</p> <p>13 in the deposition about your experience with</p> <p>14 bioequivalency studies, and I believe you only got</p> <p>15 as far as maybe in your first year of residency at</p> <p>16 the University of Kentucky, or maybe undergrad.</p> <p>17 Have you had other experience</p> <p>18 working with, conducting, bioequivalency studies?</p> <p>19 A. Yeah. When I first started</p> <p>20 faculty at the University of Tennessee, that would</p> <p>21 have been 1983, I was probably involved in and</p> <p>22 analyzed and published maybe a dozen</p> <p>23 pharmacokinetic-based bioavailability studies with</p> <p>24 a variety of cardiovascular drugs. And so those</p> <p>25 are all publications that are -- that are in my</p>	<p style="text-align: right;">Page 245</p> <p>1 A. Let's see. "Active ingredient is</p> <p>2 any component that is intended to furnish</p> <p>3 pharmacologic activities or other direct effect of</p> <p>4 the diagnosis, cure, mitigation, treatment, or</p> <p>5 prevention of disease, or to affect the structure</p> <p>6 of function of the body in man or -- or animals,"</p> <p>7 if it's veterinary products.</p> <p>8 "The term includes those</p> <p>9 components that may undergo chemical change in the</p> <p>10 manufacture of the drug product and be present in</p> <p>11 the drug product in a modified form intended to</p> <p>12 furnish the specified activity or effect."</p> <p>13 So it's an intended act or</p> <p>14 ingredient.</p> <p>15 Q. Thank you.</p> <p>16 And can you read Inactive</p> <p>17 Ingredient, please?</p> <p>18 MR. VAUGHN: Steve? Steve, I'm</p> <p>19 still not seeing this document in the</p> <p>20 exhibit folder. I've refreshed it</p> <p>21 several times.</p> <p>22 MR. FOWLER: Tim's working</p> <p>23 vigorously.</p> <p>24 MR. VAUGHN: He's working on</p> <p>25 dropping it in, is that what you said?</p>

<p style="text-align: right;">Page 246</p> <p>1 MR. FOWLER: Yeah. He's working 2 on it. I threw him a curve ball. 3 Sorry. 4 MR. VAUGHN: All right. 5 MR. FOWLER: He wasn't ready for 6 that one. 7 MR. VAUGHN: Not a problem. 8 BY MR. FOWLER: 9 Q. Doctor, can you find the 10 definition of Inactive Ingredient in that CFR 11 document? 12 A. Yes. That's on page -- 13 Q. They're alphabetical, aren't 14 they? 15 A. Yeah. That's on page 5 of 11 in 16 that document. It's any component other than the 17 active ingredient. 18 Q. Is that what it says? 19 A. That's what it -- 20 Q. Can you read it verbatim? 21 A. "Inactive ingredient is any 22 component other than active ingredient." 23 So that would cover contaminants, 24 impurities, excipients, or whatever. 25 Q. It refers to specifically the</p>	<p style="text-align: right;">Page 248</p> <p>1 it's uncommon when companies are making generic 2 products, sometimes on the first run, to have 3 something that ends up not being bioequivalent and 4 requires going back to the drawing board and 5 altering particle size or some other component of 6 the formulation until they -- until they get the 7 product that is going to be bioequivalent that 8 would then be FDA approved, the ANDAs approved, 9 and then it's allowed to be given to patients as 10 an AB-rated generic drug. 11 That's not, I don't believe, 12 uncommon. I don't have statistics on that, but I 13 think it's unrealistic to expect them to get it 14 right on the first time every single time. And 15 those are -- as long as those are disclosed to the 16 FDA that we made this change and now we want this 17 approved, and then the FDA approves it. And so 18 all the ANDAs that I -- I included in my report 19 were FDA reviewed, approved, AB-rated and allowed 20 to be generically substituted for a brand name 21 valsartan product. 22 Q. Did any of the BE documents, even 23 including the failed ones that counsel showed you, 24 did any of those show that the valsartan's 25 bioequivalence was affected by the presence of</p>
<p style="text-align: right;">Page 247</p> <p>1 components, doesn't it? 2 A. Yes. 3 Q. Can you read the definition for a 4 Component? 5 MR. VAUGHN: May the record 6 reflect as the Defense counsel 7 repeatedly objected to any type of 8 regulatory questions or opinions and now 9 is solely focussed on regulatory 10 questions. 11 THE WITNESS: "Component is any 12 ingredient intended for use in the 13 manufacture of a drug product, including 14 those that may not appear in such drug 15 product." 16 So that could be a lot of 17 excipients and those kinds of things. 18 BY MR. FOWLER: 19 Q. Thank you. 20 Doctor, have you seen anything in 21 the documents that -- that Plaintiffs' counsel has 22 shown you today with regard to the ANDAs or the 23 bioavailability studies that change -- change any 24 of your opinions in this case? 25 A. No. And -- and I don't think</p>	<p style="text-align: right;">Page 249</p> <p>1 other compounds, whether they be, you know, 2 amlodipine, HCTZ or the combination thereof? 3 A. Yeah, again, we don't know which 4 did or didn't have NDMA, but inclusion of the 5 combination products was demonstrated to support a 6 scientific conclusion that without an overlapping 7 either metabolism or drug distribution system, 8 that those compounds in with valsartan, even in 9 milligram quantities, much less microgram 10 quantities, would not be expected to have any 11 altering effect on the bioequivalence, and 12 therefore the therapeutic response to valsartan. 13 Q. Regard to -- I'm showing you what 14 was marked as Exhibit 19. This, I'll refer to it 15 as the bankruptcy document with regard to PRACS. 16 Is there any mention of valsartan or valsartan 17 testing anywhere in that document? 18 A. No. 19 Q. With regard to the -- with regard 20 to Exhibit 20, Doctor, do you recall the -- the 21 questions concerning Cetero's bioequivalence data 22 and FDA's investigation of that? 23 I'm showing you 20 -- Exhibit 20. 24 Do you recall those questions, the questions on 25 the document?</p>

<p>Page 250</p> <p>1 A. Yes.</p> <p>2 Q. Can you turn to the second page</p> <p>3 and identify what are the drugs that those ANDAs</p> <p>4 of reference in that Exhibit 20, what are those</p> <p>5 drugs?</p> <p>6 A. Federal Register Notices on</p> <p>7 October 28th. "The agency is proposing to</p> <p>8 withdraw Watson's Oxycodone/ibuprofen ANDA and</p> <p>9 InvaGen's Trandologril (phonetic) ANDA."</p> <p>10 Q. Is there anything in that</p> <p>11 document that suggests FDA was critical of any</p> <p>12 testing of the valsartan bioequivalence, if any</p> <p>13 was done at all at that -- by that company at that</p> <p>14 location?</p> <p>15 A. No mention of valsartan at all.</p> <p>16 Q. Doctor, can you explain why it is</p> <p>17 that you spent the time reviewing the BE data from</p> <p>18 each of the various generic manufacturers for the</p> <p>19 various drugs, whether it's valsartan by itself or</p> <p>20 in combination? What was the im- -- what was the</p> <p>21 importance? What was -- why did you review those</p> <p>22 -- that data, and how did it factor into your</p> <p>23 opinion?</p> <p>24 MR. VAUGHN: Object to the form.</p> <p>25 THE WITNESS: Again, from a pure</p> <p>Page 251</p> <p>1 scientific standpoint, if two compounds</p> <p>2 that are known to be in the same tablet,</p> <p>3 let's say, have the chance to interfere</p> <p>4 with each other altering the effect of</p> <p>5 certainly the intended compound, in this</p> <p>6 case valsartan, then I wrote a -- a</p> <p>7 fairly lengthy section in my report</p> <p>8 about what are the different mechanisms</p> <p>9 whereby there would be an interruption</p> <p>10 of the valsartan effectiveness. It had</p> <p>11 to be its absorption, it had to be its</p> <p>12 metabolism, it had to be its hepatic</p> <p>13 distribution, or its effect at the</p> <p>14 angiotensin II receptor site.</p> <p>15 And there's no mechanism whereby</p> <p>16 NDMA or NDEA can do that. There's no</p> <p>17 mechanism whereby hydrochlorothiazide,</p> <p>18 which is in there, can do that. And</p> <p>19 there is no mechanism where amlodipine</p> <p>20 does that. So none of those substances</p> <p>21 have any mechanisms to alter either the</p> <p>22 kinetics or the therapeutic response to</p> <p>23 valsartan.</p> <p>24 BY MR. FOWLER:</p> <p>25 Q. You were shown -- let me, for</p>	<p>Page 252</p> <p>1 example, hand you Exhibit 14 -- hand you</p> <p>2 Exhibit 14 (tendering) -- and direct your</p> <p>3 attention to the table showing the BE results.</p> <p>4 Let me know when you're there.</p> <p>5 A. I'm there.</p> <p>6 Q. The BE results were outside of</p> <p>7 the 80 to -- is it 120 is the FDA range?</p> <p>8 A. 125.</p> <p>9 Q. When they are -- when the BE</p> <p>10 results as reflected there in Exhibit 14 were</p> <p>11 outside the range, do you attribute any of that to</p> <p>12 any presence of NDMA or NDEA?</p> <p>13 A. No. Again, this is usually due</p> <p>14 to some type of tableting issue and -- and</p> <p>15 particle size. So it's -- it's -- I would not</p> <p>16 attribute it to NDEA or NDMA at all.</p> <p>17 Q. Based on your understanding of</p> <p>18 the science of the bioequivalence study process,</p> <p>19 can you explain what reformulation does and how</p> <p>20 that would translate to different results of the</p> <p>21 BE studies?</p> <p>22 MR. VAUGHN: Object to the form.</p> <p>23 THE WITNESS: Yeah, again, this</p> <p>24 starts getting into a pharmaceuticals</p> <p>25 process that's a little bit -- I've had</p> <p>Page 253</p> <p>1 a little bit of training in that and --</p> <p>2 and understanding and have read some</p> <p>3 articles throughout the years.</p> <p>4 But it's mostly involving the --</p> <p>5 the tableting, the particle size, the</p> <p>6 pressure with which you compress the</p> <p>7 tablet, the film coating, the things</p> <p>8 that result in the tablet disintegrating</p> <p>9 and then releasing the active</p> <p>10 ingredient.</p> <p>11 And so it's -- it's more of a</p> <p>12 pharmaceuticals development, tinkering</p> <p>13 that you do with your products to get</p> <p>14 the intended dissolution and then</p> <p>15 ultimate bioequivalence that you're</p> <p>16 looking for.</p> <p>17 BY MR. FOWLER:</p> <p>18 Q. Does the fact that some of the</p> <p>19 studies, the BE studies you were shown by counsel,</p> <p>20 were studies under 100 percent males and 100</p> <p>21 percent Asian males, does that have any impact on</p> <p>22 -- first of all, on the validity of the BE</p> <p>23 results?</p> <p>24 A. No. Again, the FDA allowed those</p> <p>25 studies to be done and approves the ANDAs in the</p>
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1 face of those. And remember, what you're doing
2 with the bioequivalence study in the same person
3 is comparing test product with reference products.
4 And then you take it to another
5 person and you test, test product versus reference
6 product. And the fact that that, both times, was
7 in a male or that they weighed 60 kilograms, if
8 you then take that same release characteristic to
9 a female or a person that weighs 78 kilos or a
10 person that's 39 instead of 29, you're still
11 within that same person going to see the -- the
12 approvable release characteristics in that --
13 between those two products. It'll retain its
14 bioequivalence.
15 Q. Do the test subjects or the test
16 methodology of the BE studies, that you were
17 shown, impact your opinion with regard to the
18 presence of NDMA and its impact, if any, on
19 bioequivalence?
20 A. I think it's --
21 MR. VAUGHN: Object to form.
22 THE WITNESS: -- a similar
23 question worded slightly -- I'm sorry,
24 go ahead.
25 MR. VAUGHN: I -- object to form.

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1 You're good.
2 THE WITNESS: Okay. I think it's
3 a similar question asked a slightly
4 different way, and -- and as I've stated
5 multiple times today -- and it's in my
6 report -- the presence of NDMA and NDEA,
7 there's no mechanism, no scientific
8 rationale beyond how they could alter
9 the bioequivalence of any of the
10 valsartan products.
11 BY MR. FOWLER:
12 Q. Would that be true for either
13 gender or any race, in your opinion?
14 A. Yeah, that's -- would be
15 independent of those issues.
16 Q. Early in the deposition, there
17 were questions about the circulation of -- of
18 blood.
19 Do you recall those questions?
20 A. Uh-huh. Yes. Sorry.
21 Q. And does -- how, if at all, does
22 the blood circulation play a role in your opinions
23 in this case with regard to the NDMA and -- and
24 the valsartan?
25 MR. VAUGHN: Object to form.

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1 THE WITNESS: In -- in the
2 context that we were talking about at
3 that time, we were talking about the
4 ability to measure an elimination
5 half-life and how that's affected by
6 blood flow, liver blood flow. You can
7 only measure that if there's drug in the
8 blood. And with NDMA at the amounts
9 that we're talking about, that has to be
10 given intravenously, and then you can
11 measure the decline in blood because it
12 started there and you watch it go down.
13 And some of that blood flow goes to the
14 liver, some goes to the heart, some goes
15 to the lungs, you know, whatever.
16 That issue doesn't apply when you
17 talk about giving low doses of these
18 high-clearance drugs in an oral format
19 that don't reach the systemic
20 circulation. You can't measure a
21 half-life in a situation where there's
22 no measurable drug there to begin with.
23 BY MR. FOWLER:
24 Q. Doctor, directing your attention
25 to your report. Do you have that in front of you?

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1 A. I do.
2 Q. Has counsel asked you about all
3 of your opinions in your report today?
4 A. Pretty much focussed on -- on
5 bioequivalence, I would say.
6 Q. Do you have -- turning your
7 attention to page 52. Do you see a Summary of
8 Opinions and Conclusions section?
9 A. Yes.
10 Q. Would you please read both of
11 those points on page 52 going over to 53 to the
12 third point, please?
13 A. Okay. There are three main
14 points that I addressed in -- in my report, and
15 they're -- they're summarized on the end of page
16 52 and at the beginning of page 53.
17 The first is relevant to what we
18 had a lot of questions on today, and it basically
19 is that the presence of NDMA and NDEA in valsartan
20 could not have had any effect on the kinetics,
21 dynamics, bioavailability or bioequivalence of
22 valsartan generic products because there's --
23 Q. Just please -- just read your --
24 read from your paragraph, please.
25 A. Oh, read it verbatim?

<p>Page 258</p> <p>1 Q. Yes, sir.</p> <p>2 A. I'm sorry.</p> <p>3 Q. You were doing fine.</p> <p>4 A. "The compounds do not share any</p> <p>5 known pharmacokinetic or pharmacodynamic</p> <p>6 mechanism. The presence of active intended</p> <p>7 ingredients with valsartan, such as</p> <p>8 hydrochlorothiazide or amlodipine, also did not</p> <p>9 alter valsartan bioequivalence for the same</p> <p>10 reasons, so there is no overlapping</p> <p>11 pharmacokinetic process. Thus, there is no</p> <p>12 conceivable way for NDMA or NDEA, merely by being</p> <p>13 present, to alter the bioequivalence of valsartan,</p> <p>14 and thus its therapeutic response and efficacy."</p> <p>15 Q. Thank you. And you have another</p> <p>16 opinion?</p> <p>17 A. And my second opinion gets back</p> <p>18 to this concept of first pass metabolism. "The</p> <p>19 levels of NDMA or NDEA that the FDA has detected</p> <p>20 in affected valsartan tablets, when these are</p> <p>21 taken on a daily basis, would not exceed the</p> <p>22 liver's capacity to metabolize the NDMA or the</p> <p>23 NDEA contained in those tablets in a first pass</p> <p>24 metabolism process. And according-" --</p> <p>25 "accordingly, NDMA or NDEA is unlikely to reach</p>	<p>Page 260</p> <p>1 A. Yes.</p> <p>2 Q. We also marked --</p> <p>3 MR. FOWLER: I think we're up to</p> <p>4 Exhibit 37 [sic], Counsel.</p> <p>5 BY MR. FOWLER:</p> <p>6 Q. -- simply the list of materials</p> <p>7 considered that was provided to you. I just</p> <p>8 wanted to mark that as an exhibit.</p> <p>9 (Exhibit 38 was marked.)</p> <p>10 BY MR. FOWLER:</p> <p>11 Q. Doctor, do you recognize that as</p> <p>12 your Materials Considered list?</p> <p>13 A. Yes.</p> <p>14 Q. And then Exhibit 38 [sic] is --</p> <p>15 MR. FOWLER: Counsel, I'm holding</p> <p>16 up the flash drive of Dr. Bottorff's</p> <p>17 Materials Considered. So we're going to</p> <p>18 send this to the court reporter as we've</p> <p>19 done in other depositions and be copied</p> <p>20 that way.</p> <p>21 This is Exhibit 38 [sic]. Madam</p> <p>22 Court Reporter, we'll mail that to you.</p> <p>23 (Late-filed Exhibit 39 was</p> <p>24 marked.)</p> <p>25 BY MR. FOWLER:</p>
<p>Page 259</p> <p>1 the systemic circulation or other organ systems</p> <p>2 outside of the liver; therefore, there is no</p> <p>3 scientific basis to assume that there is any</p> <p>4 increased risk to other organ systems which</p> <p>5 support the medical monitoring that is proposed by</p> <p>6 Plaintiffs' expert Dr. Kaplan."</p> <p>7 Q. Thank you.</p> <p>8 And on the -- on the next page,</p> <p>9 do you have another opinion?</p> <p>10 A. I have another opinion, and --</p> <p>11 and this was more of a mathematical. "Based on</p> <p>12 the known pharmacokinetic principles of</p> <p>13 accumulation, the daily exposure" -- which in this</p> <p>14 case is usually every 24 hours -- "to NDMA or NDEA</p> <p>15 would not accumulate, given the known elimination</p> <p>16 half-life of these compounds, which are in" --</p> <p>17 "measured in minutes."</p> <p>18 So to give something that's gone</p> <p>19 in three to five half-lives, of a five- to</p> <p>20 ten-minute elimination rate, there's no way, given</p> <p>21 that once every 24 hours, could lead to any type</p> <p>22 of accumulation at all.</p> <p>23 Q. Do you hold those opinions to a</p> <p>24 reasonable degree of medical -- of scientific</p> <p>25 certainty?</p>	<p>Page 261</p> <p>1 Q. If you'll indulge us for a</p> <p>2 moment, I may be about finished.</p> <p>3 My much more attentive colleague</p> <p>4 has pointed out that the Materials Considered is</p> <p>5 38 and the flash drive should be 39, so we'll just</p> <p>6 fix that.</p> <p>7 And with that, I'll -- I'll -- I</p> <p>8 have no further questions.</p> <p>9 Thank you very much, Doctor.</p> <p>10 MR. FOWLER: Counsel.</p> <p>11 MR. VAUGHN: Can you just give me</p> <p>12 five minutes to consult with my</p> <p>13 cocounsel? I'll be right back. We'll</p> <p>14 be real quick.</p> <p>15 THE VIDEOGRAPHER: Shall we go</p> <p>16 off the record?</p> <p>17 MR. VAUGHN: Please.</p> <p>18 THE VIDEOGRAPHER: The time is</p> <p>19 4:51 p.m. We're off the record.</p> <p>20 (Brief recess observed.)</p> <p>21 THE VIDEOGRAPHER: 4:56 p.m.,</p> <p>22 we're back on the record.</p> <p>23 EXAMINATION</p> <p>24 BY MR. VAUGHN:</p> <p>25 Q. Dr. Bottorff, do all of your</p>

<p style="text-align: right;">Page 262</p> <p>1 opinions contained within your class action expert 2 report apply equally to all potential class 3 members? 4 A. I'm not sure exactly what that 5 question means. What -- what -- what does that 6 mean exactly so I can better answer it? 7 Q. Which part of the question are 8 you having trouble with? 9 A. Well, maybe start with the 10 definition of the class members. Are they the 11 people who have filed, like, claims or.... 12 Q. I -- I understand now, Doctor. 13 Do all of your opinions contained 14 within your class action expert report apply 15 equally to all of the Defendants? 16 A. Again, I don't know if I had 17 bioequivalence data on -- well, from every 18 Defendant, but I -- I think it does because of the 19 reasons behind it. It doesn't matter that NDMA 20 may have been in there or not. It wouldn't affect 21 the bioequivalence. So I guess I would say yes. 22 Q. As a pharmacist, if you are in 23 possession of an adulterated drug, would you 24 return that adulterated drug to a manufacturer, or 25 would you just throw it away?</p>	<p style="text-align: right;">Page 264</p> <p>1 destruction process that is not flushing 2 them down the toilet. So that's just 3 not how it happens these days. 4 BY MR. VAUGHN: 5 Q. All right. Regardless, you 6 wouldn't be able to sell the contaminated drugs, 7 correct? 8 MR. FOWLER: Objection: Form, 9 outside the scope of his report and his 10 testimony and the redirect. 11 THE WITNESS: Yeah, I -- again, 12 in -- in your hypothetical, you would 13 have to know that something was 14 adulterated, so I don't -- I don't know 15 what that process is. 16 BY MR. VAUGHN: 17 Q. As a pharmacist, if the FDA would 18 not let you sell a drug to the U.S. public, what 19 would you do? Would you be able to get your money 20 back from the manufacturer? 21 MR. FOWLER: Objection, form. 22 This is outside the scope of his 23 entire report, of his testimony, and 24 outside of my redirect. Nothing about 25 The redirect opened up questions for</p>
<p style="text-align: right;">Page 263</p> <p>1 MR. FOWLER: Objection: Form, 2 scope. 3 THE WITNESS: I've never been in 4 that position of -- in -- in that type 5 of practice. I guess I would follow 6 whatever my -- my company's policy was. 7 But I don't -- I don't know what that 8 is. I don't know what that would be. 9 BY MR. VAUGHN: 10 Q. Would you be afraid of 11 contaminating the groundwater if you're just 12 throwing away drugs that are contaminated with 13 carcinogens? 14 MR. FOWLER: Objection, outside 15 the scope of my redirect completely. 16 MR. VAUGHN: Your redirect had 17 him answer quest- -- testifying on every 18 single one of his opinions. You 19 completely opened the scope up. 20 THE WITNESS: Well, what I can 21 answer is that that's not how in 22 pharmacies that we get rid of drugs 23 anymore. There are drug take-back 24 programs that almost every pharmacy runs 25 periodically, and there's some</p>	<p style="text-align: right;">Page 265</p> <p>1 what a pharmacist is going to sell, 2 Counsel. 3 MR. VAUGHN: He -- he submitted 4 an expert report in a class action 5 saying this stuff is worth money. 6 MR. FOWLER: You should have 7 asked him about that in your case in 8 chief here on -- on direct. You're 9 going back, for whatever reason. It's 10 outside the scope, and I would have 11 objected to it in the first place. 12 MR. VAUGHN: You did object to it 13 a bunch in the first place and then you 14 were coaching the witness before and 15 then you opened everything back up by 16 having him read every one of his 17 opinions. You opened the scope. 18 MR. FOWLER: I'm not going to 19 argue with you, Counsel. The words 20 "sell the drugs" was nowhere in his 21 opinions. 22 BY MR. FOWLER: 23 Q. If you can't sell a drug -- 24 (Unintelligible overlapping.) 25 BY MR. VAUGHN:</p>

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1 Q. -- Doctor, does it have any
2 value?
3 MR. FOWLER: I'm sorry, I spoke
4 over you, Counsel. Please state that
5 again.
6 THE WITNESS: Or I -- I never
7 answered the previous question.
8 MR. FOWLER: He withdrew.
9 THE WITNESS: Oh, okay.
10 MR. FOWLER: So a new question.
11 Go ahead.
12 BY MR. VAUGHN:
13 Q. Would you like to answer the
14 previous -- would you like to answer the previous
15 question, Doctor?
16 A. If you would like me to.
17 Q. So as a pharmacist, if the FDA
18 will not allow you to sell a drug to the U.S.
19 public, would you be able to get your money back
20 from the manufacturer?
21 MR. FOWLER: Same objection.
22 THE WITNESS: And I would say
23 that I've never been in the situation to
24 understand how that works. That's not
25 my -- my academic career has been

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1 working in hospitals with cardiology
2 patients and cardiologists, and I've
3 never worked in that environment, so I
4 -- I had no experience with that at all.
5 BY MR. VAUGHN:
6 Q. If you can't sell the drug,
7 Doctor, does the drug have any value?
8 MR. FOWLER: Form,
9 incomprehensible.
10 THE WITNESS: Again, I -- I mean,
11 in a hypothetical, if you can't sell it,
12 then obviously you can't sell it, so....
13 BY MR. VAUGHN:
14 Q. Absolutely.
15 A. So I would say, yeah, if you
16 can't sell it -- so it doesn't have value if you
17 can't sell it.
18 MR. VAUGHN: I have no further
19 questions.
20 MR. FOWLER: He'll read.
21 MR. VAUGHN: Thanks for your time
22 again, Dr. Bottorff.
23 MR. FOWLER: Nothing further.
24 THE VIDEOGRAPHER: The time is
25 5:02 p.m. This concludes today's

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1 testimony from Dr. Michael Bottorff.
2 We are now off the record.
3 FURTHER DEPONENT SAITH NOT.
4 (Proceedings concluded at 4:02
5 p.m. Eastern.)
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1 REPORTER'S CERTIFICATE
2 I certify that the witness in the
3 foregoing deposition, MICHAEL BOTTORFF, PHARM.D.,
4 was by me duly sworn to testify in the within
5 entitled cause; that the said deposition was
6 taken at the time and place therein named; that
7 the testimony of said witness was reported by me,
8 a Shorthand Reporter and Notary Public of the
9 State of Tennessee authorized to administer oaths
10 and affirmations, and said testimony, Pages 7
11 through 258 thereafter transcribed into
12 typewriting.
13 I further certify that I am not of counsel
14 or attorney for either or any of the parties to
15 said deposition, nor in any way interested in the
16 outcome of the cause named in said deposition.
17 IN WITNESS WHEREOF, I have hereunto set my
18 hand this 4th day of April 2022.
19
20
21
22
23
24
25

Carissa L. Boone, LCR No. 382
My License Expires: 6/30/2022

1 ERRATA

2

I, MICHAEL BOTTORFF, PHARM.D., having
3 read the foregoing deposition, Pages 7 through
268, taken March 25, 2022, do hereby certify said
4 testimony is a true and accurate transcript, with
the following changes (if any):

5

6 PAGE LINE CHANGE REASON

7

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MICHAEL BOTTORFF, PHARM.D.

21

22

23

Notary Public

24

My Commission Expires: _____

25

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Exhibit 207

1 IN THE UNITED STATES DISTRICT COURT
2 DISTRICT OF NEW JERSEY
3 CAMDEN DIVISION
4
5 IN RE: VALSARTAN)
 LOSARTAN, AND IRBESARTAN)
6 PRODUCTS LIABILITY)
 LITIGATION)
7)
) No. 2875
8)
) HON. ROBERT B. KUGLER
9 This Document Relates to)
 All Actions)
10)
)

11
12 CONFIDENTIAL INFORMATION
13 SUBJECT TO PROTECTIVE ORDER
14 REMOTE
15 VIDEO-RECORDED
16 EXPERT WITNESS TESTIMONY OF
17 DAVID C. CHAN, JR., M.D.

18
19 Thursday, March 3, 2022, 7:49 a.m.
20 - - - -

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22
23
24 REPORTED BY: ELAINA BULDA-JONES, CSR 11720
25

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<p>Page 7</p> <p>1 THE VIDEOGRAPHER: We are now on the</p> <p>2 record. My name is Joseph Mourgos. I am a</p> <p>3 videographer for Golkow Litigation Services.</p> <p>4 Today's date is March 3rd, 2022, and the</p> <p>5 time on the video monitor is 7:49 a.m. Pacific time.</p> <p>6 This remote video deposition is being held</p> <p>7 in the matter of Valsartan, Losartan and Irbesartan</p> <p>8 Products Liability Litigation MDL Number 2875 for</p> <p>9 the United States District Court, District of</p> <p>10 New Jersey.</p> <p>11 The deponent is Dr. David Chan.</p> <p>12 All parties to this deposition are</p> <p>13 appearing remotely and have agreed to the witness</p> <p>14 being sworn in remotely.</p> <p>15 Due to the nature of remote reporting,</p> <p>16 please pause briefly before speaking to ensure all</p> <p>17 parties are heard completely.</p> <p>18 Counsel has been noted on the stenographic</p> <p>19 record.</p> <p>20 The court reporter is Elaina Bulda-Jones</p> <p>21 and she will now administer the oath.</p> <p>22 DAVID C. CHAN, JR., M.D.,</p> <p>23 called as a witness by the Plaintiffs herein, being</p> <p>24 first duly sworn by the Certified Shorthand Reporter</p> <p>25 was thereupon examined and testified as is</p>	<p>Page 9</p> <p>1 would impede your ability to recall events or</p> <p>2 testify truthfully?</p> <p>3 A. No.</p> <p>4 Q. Okay. This is not a marathon session.</p> <p>5 You know, we're not going to try to go through the</p> <p>6 whole thing in one -- one shot. So if -- and I know</p> <p>7 you're a doctor, so obviously, if you have an urgent</p> <p>8 patient call, just tell us, you know, because we</p> <p>9 want you to take care of your patients, you know.</p> <p>10 We understand that.</p> <p>11 So, you know, and we will take breaks, you</p> <p>12 know, and if you need a break just ask for one and</p> <p>13 as long as there's not a, you know, question</p> <p>14 pending, that -- that's totally fine, fair?</p> <p>15 A. Yes, thank you.</p> <p>16 Q. In the other depositions that you had,</p> <p>17 when were those depositions?</p> <p>18 A. I believe they were within the last year</p> <p>19 or two.</p> <p>20 Q. Okay. Got it.</p> <p>21 And I -- you know, we're taking this</p> <p>22 deposition remotely, obviously.</p> <p>23 Do you have anybody else in the room with</p> <p>24 you there?</p> <p>25 A. No.</p>

<p style="text-align: right;">Page 10</p> <p>1 Q. Do you have any documents with you?</p> <p>2 A. No.</p> <p>3 Q. Okay. Great.</p> <p>4 Did you see the deposition notice that we</p> <p>5 sent over in this case?</p> <p>6 A. Are you referring to the most recent one</p> <p>7 about a week -- within a week of this?</p> <p>8 Q. That's right.</p> <p>9 A. I believe I was forwarded either the</p> <p>10 notice or some snippet of the notice.</p> <p>11 Q. Got it.</p> <p>12 I'm going to try to share it with you, so</p> <p>13 forgive me if I fumble with this technology because</p> <p>14 I might. But I'm going to do my best to put this</p> <p>15 into your folder because we're going to have</p> <p>16 exhibits, obviously. And I'm going to -- I watched</p> <p>17 the video, and we'll see if it works. I should</p> <p>18 have, perhaps, practiced this.</p> <p>19 Okay. I believe I put your deposition</p> <p>20 notice in the marked exhibits folder.</p> <p>21 A. Okay. Yep, I'm seeing it now.</p> <p>22 Q. Okay. Great.</p> <p>23 MR. MIGLIACCIO: I want to mark that as</p> <p>24 Exhibit 1. I'm not quite sure how to do that but we</p> <p>25 can address that.</p>	<p style="text-align: right;">Page 12</p> <p>1 Q. I'm referring to that, and I'm referring</p> <p>2 to what we've asked for here in Exhibit A.</p> <p>3 A. Okay.</p> <p>4 Q. So in other words, if there's anything</p> <p>5 that we've asked for here that maybe wasn't included</p> <p>6 on the materials considered list or otherwise not</p> <p>7 provided to -- to us.</p> <p>8 A. That would inform my opinions in the</p> <p>9 report?</p> <p>10 Q. Correct.</p> <p>11 A. Okay. So there was -- there's no other</p> <p>12 document, specific document informing my opinions in</p> <p>13 the report other than my expertise as a physician</p> <p>14 and as a health economist.</p> <p>15 Q. Were there any documents or materials that</p> <p>16 you reviewed in preparation for this deposition that</p> <p>17 were not included in the materials that were</p> <p>18 produced to us?</p> <p>19 A. No.</p> <p>20 Q. So you -- fair to say, then, you haven't</p> <p>21 looked at anything other than the materials that</p> <p>22 you've provided?</p> <p>23 A. The materials on the materials considered</p> <p>24 list; is that right? Yes.</p> <p>25 Q. And the materials that have been provided</p>
<p style="text-align: right;">Page 11</p> <p>1 (Whereupon, Chan Exhibit 1 was marked for</p> <p>2 identification.)</p> <p>3 BY MR. MIGLIACCIO:</p> <p>4 Q. Is this the document that you saw?</p> <p>5 A. I don't think I saw the entire document.</p> <p>6 I think I saw some of the questions and document</p> <p>7 requests.</p> <p>8 Q. Okay. I'm going to look.</p> <p>9 So Exhibit A, which is on page 3, contains</p> <p>10 document requests, right?</p> <p>11 A. Correct.</p> <p>12 Q. Okay. Did you search for those documents</p> <p>13 that were requested?</p> <p>14 A. To the extent that I had the relevant</p> <p>15 documents.</p> <p>16 Q. Was there anything that you were not able</p> <p>17 to find?</p> <p>18 A. No.</p> <p>19 Q. Okay. Were there any documents that you</p> <p>20 reviewed in forming your opinion that were not</p> <p>21 included in the documents that you provided to your</p> <p>22 lawyers and, you know, to us?</p> <p>23 A. Are you referring to the materials</p> <p>24 considered list that informed my opinion in the</p> <p>25 report?</p>	<p style="text-align: right;">Page 13</p> <p>1 to us now?</p> <p>2 A. Correct.</p> <p>3 Q. Okay. Were there any documents that you</p> <p>4 wanted to review but you couldn't get or otherwise</p> <p>5 were not provided?</p> <p>6 A. No.</p> <p>7 Q. Okay. What did you do to prepare for your</p> <p>8 deposition?</p> <p>9 A. What did I do to prepare for this</p> <p>10 deposition in particular or what did I do during the</p> <p>11 course of the case to form my opinions?</p> <p>12 Q. Just to prepare for this deposition in</p> <p>13 particular.</p> <p>14 A. Okay. I reviewed the report. I reviewed</p> <p>15 some of the other reports from Conti, Song, and</p> <p>16 Kaplan.</p> <p>17 I had phone calls with the lawyers, and I</p> <p>18 had phone calls with Analysis Group.</p> <p>19 Q. Who is Analysis Group?</p> <p>20 A. Analysis Group is an economic consulting</p> <p>21 firm.</p> <p>22 Q. And where -- where are they located?</p> <p>23 A. I believe they have a number of different</p> <p>24 offices. Most of the people that I worked with are</p> <p>25 in the Boston office, but there are also people --</p>

<p>Page 14</p> <p>1 there's one person that I worked with who's in the 2 Menlo Park office. 3 Q. And when you said you had phone calls with 4 the Analysis Group who did you speak with at the 5 Analysis Group? 6 A. The people that I was in most contact with 7 include several people. So they include Jessica Lu, 8 Michaela Johnson, Brian Ellman, Richard Mortimer, 9 and Molly Frean. 10 Those were the people that I had the most 11 contact with. 12 Q. So can you tell me who those people are 13 and we can ask -- I'll ask you about them later when 14 we go through your invoice. 15 But can you just briefly tell me who 16 those -- those individuals are? 17 A. Sure. 18 MR. STOY: Object to the form. 19 Go ahead. 20 THE WITNESS: Do you -- could you be a 21 little bit more specific about what do you mean by 22 who they are? 23 BY MR. MIGLIACCIO: 24 Q. Well, I know they work for the Analysis 25 Group. You know, what is -- you know, what is their</p>	<p>Page 15</p> <p>1 position and how -- what did they do in terms of 2 working with you? 3 MR. STOY: Object to the form. 4 THE WITNESS: So I can tell you that two 5 of them are partners. Richard Mortimer and Brian 6 Ellman are partners. 7 Other members are managers or people that 8 I think are at the level below partners but have 9 quite a bit of experience and, you know, have 10 advanced degrees in economics or management. Those 11 include Michaela Johnson and Jessica Lu. 12 Molly Frean is another analyst who has a 13 Ph.D. in health policy or health economics. 14 And I believe those are the people that I 15 mentioned that I interacted mostly with. 16 BY MR. MIGLIACCIO: 17 Q. Any physicians in that group? 18 A. No. 19 Q. Okay. Are you the only physician, then, I 20 guess, who worked on this report? 21 A. Of the people that I mentioned, I'm the 22 only physician. There could be other people at 23 Analysis Group that performed very -- that performed 24 a role that -- like a role to check the quality 25 control, the document, or look at the code, for</p>	<p>Page 16</p> <p>1 example, that I don't know exactly who they are. 2 And I can't rule out that there might be 3 some physicians in that group. 4 Q. Who -- who worked on your report? 5 A. Who, for example, might have kind of 6 checked for typos or who might have been in the -- 7 they have an extensive quality control process, I 8 believe, at Analysis Group, to, you know, check -- 9 make sure that all the references that I've looked 10 at are in there, make sure that the document is free 11 of typos, make sure the code is free of errors, make 12 sure that stuff is kind of in the correct folders in 13 the -- in the code and in the input data and the 14 exhibits. 15 So there -- I would expect that there is a 16 fairly big team involved in that, just like there's 17 a team involved in my own research that is involved 18 in quality control. 19 Q. Got it. 20 What did you, you know, read or review to 21 prepare for -- for today's deposition? 22 A. I believe I mentioned I read my report. I 23 read the reports of some of the other experts on the 24 plaintiffs' side, including Dr. Song, Dr. Kaplan, 25 and Dr. Conti.</p>	<p>Page 17</p> <p>1 I reviewed some of the primary sources 2 that I relied upon in forming my opinion. I believe 3 those are the main documents that I read in 4 preparation for this deposition. 5 Q. And I think you told me you spoke with 6 lawyers, too? 7 A. Correct. 8 Q. Who -- who did you speak with? 9 A. I don't remember all of the names of the 10 lawyers. But I spoke to Frank Stoy, who's on this 11 call. I spoke to Bob Kum. K-U-M is his last name. 12 Glenn Kerner. Kate Wittlake. 13 I believe those are -- those are the names 14 that I remember speaking to. 15 Q. And how many sessions did you have 16 speaking to -- to the lawyers? 17 A. In preparation for the deposition? 18 Q. Yes. 19 A. I don't remember exactly the number. I 20 want to say something like four sessions, three to 21 four sessions. 22 Q. How long did those sessions each take? 23 A. I think that they could have been as short 24 as two hours or three hours, and they could have 25 also been longer, more like seven hours. Around</p>
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<p style="text-align: right;">Page 18</p> <p>1 that ballpark.</p> <p>2 Q. You may have had one or more, like,</p> <p>3 seven-hour sessions?</p> <p>4 A. Maybe one, correct, one or more.</p> <p>5 Q. All right.</p> <p>6 A. Seven-hour sessions.</p> <p>7 Q. Got it. Got it.</p> <p>8 What was discussed during those sessions?</p> <p>9 MR. STOY: I'm going to object and</p> <p>10 instruct you not to answer.</p> <p>11 That question, Dr. Chan, is -- that's</p> <p>12 obviously covered by the privilege and work product</p> <p>13 doctrine.</p> <p>14 THE WITNESS: Okay.</p> <p>15 MR. MIGLIACCIO: Let me rephrase that.</p> <p>16 Q. Which documents were discussed at those --</p> <p>17 at those sessions?</p> <p>18 MR. STOY: And I'll just -- I'll just give</p> <p>19 a limiting instruction, Dr. Chan.</p> <p>20 If you know, you can answer the question</p> <p>21 about particular documents, but I'd ask you not</p> <p>22 to -- I'd instruct you not to disclose anything in</p> <p>23 particular that was discussed about any documents.</p> <p>24 THE WITNESS: Okay.</p> <p>25 MR. STOY: With that instruction, you can</p>	<p style="text-align: right;">Page 20</p> <p>1 review the state of the data, like I believe I just</p> <p>2 mentioned that, the state of the data underlying the</p> <p>3 analyses in my report.</p> <p>4 So yes, I did have calls with Analysis</p> <p>5 Group for that purpose.</p> <p>6 Q. And those -- did you have any calls in</p> <p>7 preparation for this deposition with the Analysis</p> <p>8 Group?</p> <p>9 A. Yes, that -- that was just what I</p> <p>10 mentioned.</p> <p>11 Q. Okay. Okay.</p> <p>12 That -- so that -- those calls were not --</p> <p>13 okay. I assume you also had calls with them when</p> <p>14 you were finalizing the report?</p> <p>15 A. Correct.</p> <p>16 Q. But you were just telling me about calls</p> <p>17 in preparation for the deposition?</p> <p>18 A. Right.</p> <p>19 Q. What -- so those calls were -- that --</p> <p>20 that you had with them, were after the report has</p> <p>21 been finalized, right? Because I think the report's</p> <p>22 dated January 12th.</p> <p>23 When did you have those calls with the</p> <p>24 Analysis Group that you just referenced?</p> <p>25 A. The calls -- those calls were in</p>
<p style="text-align: right;">Page 19</p> <p>1 answer.</p> <p>2 THE WITNESS: I would say that we</p> <p>3 discussed all of the documents that I mentioned in</p> <p>4 general in -- that I used in preparation for this</p> <p>5 deposition, including my report, the reports of some</p> <p>6 of the plaintiffs -- the plaintiff experts,</p> <p>7 including Dr. Song, Dr. Conti, and Dr. Kaplan.</p> <p>8 We also discussed some of the primary</p> <p>9 source material, but I can't remember exactly which</p> <p>10 ones that we discussed.</p> <p>11 BY MR. MIGLIACCIO:</p> <p>12 Q. When you refer to "primary source</p> <p>13 material," what do you mean?</p> <p>14 A. I mean the materials -- some of the</p> <p>15 materials that I considered in forming my opinions</p> <p>16 that are in my materials considered list.</p> <p>17 Q. Got it.</p> <p>18 For the -- did you have preparation</p> <p>19 sessions outside of speaking with the lawyers; in</p> <p>20 other words, did you talk to people, those other</p> <p>21 individuals at the Analysis Group to prepare?</p> <p>22 A. I had calls with the Analysis Group to</p> <p>23 review my report, to review the analyses and the</p> <p>24 data and the code underlying my report.</p> <p>25 I also had -- yeah, I also had sessions to</p>	<p style="text-align: right;">Page 21</p> <p>1 preparation for the deposition. And they were in</p> <p>2 the last two weeks.</p> <p>3 Q. Two weeks.</p> <p>4 Were any of the lawyers on those calls?</p> <p>5 A. No.</p> <p>6 Q. Okay. How many of those calls did you</p> <p>7 have with the Analysis Group?</p> <p>8 A. Maybe two.</p> <p>9 Q. Two. And how long were those sessions?</p> <p>10 A. I think they were less than four hours</p> <p>11 each, maybe three hours each.</p> <p>12 Q. Got it.</p> <p>13 Did you discuss -- and you said you were</p> <p>14 discussing the state of the data, if I -- if you</p> <p>15 could give me a little more background on that,</p> <p>16 maybe -- I didn't mean to misstate what you said, so</p> <p>17 do I have that right?</p> <p>18 A. Yes.</p> <p>19 MR. STOY: Hang on.</p> <p>20 Before you answer, Dr. Chan, I'm going to</p> <p>21 instruct you not to go into any more detail than</p> <p>22 you've already provided regarding those discussions</p> <p>23 with Analysis Group.</p> <p>24 We'd object on the same basis as before</p> <p>25 with respect to the work product.</p>

<p style="text-align: right;">Page 22</p> <p>1 Nick, you know, I allowed him to give you 2 sort of a high level overview of, you know, the 3 discussion that might have occurred with Analysis 4 Group, but we're not going to go into any more 5 detail than that. 6 MR. MIGLIACCIO: Well, Frank, I mean, I 7 think it's relevant to figure out if -- you know, if 8 the date has changed. I mean, the report was 9 submitted on the 12th of January, and that's what 10 I'm trying to drive at here. 11 MR. STOY: Well, you -- you can ask 12 Dr. Chan if the data has changed. I think he can 13 answer that question. But with respect to 14 particulars about discussions with Analysis Group, 15 my instruction's going to be not to answer those 16 questions. 17 MR. MIGLIACCIO: All right. I'll limit my 18 question for the time being to the -- to the data. 19 Q. Did the data change at the time -- did any 20 data change from the time the report was finalized 21 until now? 22 A. No, none of the data had changed. None of 23 the analyses had changed. It was purely to review 24 what I had already reviewed before. 25 Q. Okay. So there wasn't any new work done,</p>	<p style="text-align: right;">Page 24</p> <p>1 relationship with them? 2 A. I have worked with the Analysis Group on 3 other cases. 4 Q. And how long have you worked with them on 5 other cases? 6 A. I believe my first contact with the 7 Analysis Group was before the pandemic so I think 8 about two to three years. 9 Q. Okay. And I'll -- I'll get into those 10 other cases. 11 But I'll just ask you now, were those 12 other cases cases that you provided reports and/or 13 deposition testimony in? 14 MR. STOY: And before you answer, 15 Dr. Chan, I just want to give you an instruction. 16 You can answer counsel's questions for now 17 with respect to cases where you have been identified 18 as a testifying expert. 19 But for any litigations or other matters 20 where you've been retained as a nontestifying 21 consultant and haven't been publicly disclosed, I 22 would instruct you to not reveal the nature of those 23 disclosures, the parties that retained you, any of 24 that information. 25 With that instruction, you can answer the</p>
<p style="text-align: right;">Page 23</p> <p>1 then, in other words? That -- that's what I'm 2 trying to -- to find out. No subsequent analysis 3 has -- was completed? 4 A. No, that's correct. 5 Q. Okay. Did you -- did you obtain -- how 6 did you get information about this case at the -- at 7 the beginning when you were -- when you started 8 working on it? 9 A. Is your question about before I was 10 retained or after I was retained? 11 Q. Well, how about -- why don't -- I'll ask 12 it this way. 13 Why don't you tell me when you were 14 retained and then we can take it from there. 15 A. I believe I was retained around December 16 of last year. It was a pretty short timeline, 17 but -- as I recall, but I don't remember the 18 exact -- when it exactly -- when I was exactly 19 retained, but I think it was around December of last 20 year. 21 Q. And who -- who contacted you? 22 A. My initial contact was Brian Ellman at the 23 Analysis Group. 24 Q. Do you have a working relationship with 25 the Analysis Group or did you have a prior working</p>	<p style="text-align: right;">Page 25</p> <p>1 question. 2 MR. MIGLIACCIO: I'm -- I'm not asking for 3 any of that information. 4 Q. I'm just asking for where you have 5 prepared a report, you know, that you've been 6 designated as an expert or if you testified at 7 deposition. 8 MR. STOY: Thank you. 9 THE WITNESS: Thank you. 10 I don't know exactly what is in the public 11 record and what is not. I can tell you that I have 12 been deposed in some of these cases. 13 BY MR. MIGLIACCIO: 14 Q. Where you have been working with the 15 Analysis Group? 16 A. Correct. 17 Q. Got it. Okay. 18 So you said December, you think it was 19 around December of last year that you were hired? 20 A. Correct. 21 Q. Got it. 22 And you were contacted by -- I forget the 23 person's name -- can you -- somebody at the Analysis 24 Group, right? 25 A. Right. My initial contact was Brian</p>

<p style="text-align: right;">Page 26</p> <p>1 Ellman at the Analysis Group.</p> <p>2 Q. Ellman. Got it.</p> <p>3 How was that contact initiated?</p> <p>4 A. I believe the first contact was by e-mail.</p> <p>5 Q. Okay. And did you -- have you previously</p> <p>6 worked with Mr. Ellman before?</p> <p>7 A. I had been in conversations with him on</p> <p>8 another case that I was not retained on. The cases</p> <p>9 that I was retained on previously was with another</p> <p>10 individual at Analysis Group as the main contact,</p> <p>11 but I did know Brian from previous conversations.</p> <p>12 Q. Okay. And how did you decide that you</p> <p>13 would agree to -- to offer your opinion in this</p> <p>14 case?</p> <p>15 MR. STOY: Object to the form.</p> <p>16 Go ahead.</p> <p>17 THE WITNESS: Can you restate that</p> <p>18 question?</p> <p>19 BY MR. MIGLIACCIO:</p> <p>20 Q. Right.</p> <p>21 How did you come to determine that you</p> <p>22 would offer an opinion in this case?</p> <p>23 A. Is the question how did I come</p> <p>24 determine -- come to determine that I would agree to</p> <p>25 be involved in this case?</p>	<p style="text-align: right;">Page 28</p> <p>1 that I had related to the case.</p> <p>2 So I received materials that I asked for</p> <p>3 from Analysis Group. And from the lawyers, I</p> <p>4 believe I only received legal documents related to</p> <p>5 the case.</p> <p>6 Q. Were you asked -- I mean, I have a copy of</p> <p>7 your report here and we'll put it up and it's -- you</p> <p>8 know, it's lengthy, right. It's 88 pages or so.</p> <p>9 A. Yes.</p> <p>10 Q. Were you asked to render all of the</p> <p>11 opinions that are within this report initially or</p> <p>12 did the scope of your work evolve over -- over time?</p> <p>13 MR. STOY: Object to the form.</p> <p>14 You can answer.</p> <p>15 THE WITNESS: Would you like to restate</p> <p>16 your question?</p> <p>17 BY MR. MIGLIACCIO:</p> <p>18 Q. Yeah.</p> <p>19 Was -- were you asked to render all of the</p> <p>20 opinions that are here in -- in this report that --</p> <p>21 that you signed in January initially from -- from</p> <p>22 the outset or were -- or were you asked to do a</p> <p>23 smaller subset of them at the outset that later</p> <p>24 expanded?</p> <p>25 MR. STOY: Object to the form.</p>
<p style="text-align: right;">Page 27</p> <p>1 Q. That -- that's fair. Yeah.</p> <p>2 A. Okay. The initial conversation was with</p> <p>3 Brian who told me some basic information about the</p> <p>4 case. He may have provided me the complaint in the</p> <p>5 case. Then I had a discussion with the lawyers</p> <p>6 involved in the case.</p> <p>7 I believe I spent some time thinking about</p> <p>8 the questions involved in the case and what types of</p> <p>9 questions I would want to answer if I were involved</p> <p>10 in the case.</p> <p>11 Then I believe I might have had a</p> <p>12 subsequent discussion with the lawyers and then came</p> <p>13 to the conclusion that this was a case that I would</p> <p>14 agree to be involved in.</p> <p>15 Q. What -- what were you initially told about</p> <p>16 the facts? What facts were you provided initially?</p> <p>17 A. I believe I was mostly just provided legal</p> <p>18 documents involved in the case. The complaint</p> <p>19 involved in the case.</p> <p>20 Q. And did there come a point where you asked</p> <p>21 for other materials?</p> <p>22 A. I've only received legal documents from</p> <p>23 the lawyers. Analysis Group is -- is essentially</p> <p>24 assisting me in my research so I kind of -- I</p> <p>25 directed them to find materials to answer questions</p>	<p style="text-align: right;">Page 29</p> <p>1 You can answer.</p> <p>2 THE WITNESS: My assignment, are you</p> <p>3 asking about the assignment of my case, my</p> <p>4 assignment, whether my assignment was fixed from the</p> <p>5 very beginning or whether my assignment expanded</p> <p>6 over time?</p> <p>7 BY MR. MIGLIACCIO:</p> <p>8 Q. You -- you can answer that question. But</p> <p>9 I may have some further questions for you.</p> <p>10 A. My initial assignment was on the claims</p> <p>11 related to medical monitoring and that involved the</p> <p>12 reports of Dr. Song and Dr. Kaplan.</p> <p>13 I believe at a later point in the case, as</p> <p>14 I was writing my report, given my expertise as an</p> <p>15 economist, I was asked to weigh in on the claim of</p> <p>16 worthlessness by Dr. Conti.</p> <p>17 Q. Got it.</p> <p>18 So that was not part of your initial</p> <p>19 assignment when you -- when you first were retained?</p> <p>20 A. When I was first retained, I believe a lot</p> <p>21 was in flux in the case. I think there was nothing</p> <p>22 set in stone, but my initial instructions were to</p> <p>23 address the claim of medical monitoring.</p> <p>24 Q. What documents -- you said you received</p> <p>25 legal documents at the outset from the lawyers.</p>

<p style="text-align: right;">Page 30</p> <p>1 A. Right.</p> <p>2 Q. Do you recall what those documents were</p> <p>3 that you initially received?</p> <p>4 A. I received the complaint. There was a</p> <p>5 protective order I -- I believe I received. And I</p> <p>6 received reports from some of the plaintiff experts.</p> <p>7 The ones that I can remember are the reports by</p> <p>8 Dr. Song, Dr. Kaplan, and Dr. Conti.</p> <p>9 Q. Okay. When you're talking about the</p> <p>10 complaint, are you referring to the third amended</p> <p>11 medical monitoring complaint?</p> <p>12 A. I don't remember exactly what the name of</p> <p>13 the complaint was. I only received one complaint.</p> <p>14 Q. Got it.</p> <p>15 And that -- you've produced that to us, I</p> <p>16 believe; is that -- is that right?</p> <p>17 A. I believe I have.</p> <p>18 Q. Okay. And what documents did you -- I</p> <p>19 think -- what documents did you ask Analysis Group</p> <p>20 to gather for you after you received the legal</p> <p>21 documents?</p> <p>22 MR. STOY: Object to the form.</p> <p>23 Go ahead.</p> <p>24 THE WITNESS: I can't remember exactly</p> <p>25 which documents. I can tell you in general how my</p>	<p style="text-align: right;">Page 32</p> <p>1 the considerations for various patients who might be</p> <p>2 screened for cancer or who might already be screened</p> <p>3 for cancer for other reasons.</p> <p>4 So those were some of the questions that I</p> <p>5 had initially. I can't remember fully all of the</p> <p>6 questions. But those questions prompted requests</p> <p>7 for documents in a way that is consistent with the</p> <p>8 way that I do research.</p> <p>9 Q. So you had those questions and you</p> <p>10 prompted requests for -- they prompted requests for</p> <p>11 documents to Analysis Group to gather information on</p> <p>12 those questions and provide them to you?</p> <p>13 A. Correct.</p> <p>14 Q. Got it.</p> <p>15 And at Analysis Group, I think you told me</p> <p>16 there were -- there may be some physicians, but did</p> <p>17 you know of any physicians who were gathering that</p> <p>18 information for you when you asked for it?</p> <p>19 MR. STOY: Object to the form.</p> <p>20 THE WITNESS: Would you like to restate</p> <p>21 that question?</p> <p>22 BY MR. MIGLIACCIO:</p> <p>23 Q. Yeah.</p> <p>24 I think you testified that there may be</p> <p>25 some physicians at Analysis Group originally, and I</p>
<p style="text-align: right;">Page 31</p> <p>1 research process works if that would be helpful.</p> <p>2 BY MR. MIGLIACCIO:</p> <p>3 Q. Yeah, let me -- I'll ask you another</p> <p>4 question, then. I'll -- I do -- I'll get into that.</p> <p>5 I think you said, "I directed them to find</p> <p>6 materials to answer questions that I had related to</p> <p>7 the case."</p> <p>8 What initial questions did you have</p> <p>9 related to the case that you sought answers --</p> <p>10 sought -- sought documents for?</p> <p>11 A. I can't remember all of the initial</p> <p>12 questions. I would say that my questions could be</p> <p>13 organized in a way that very much reflects the</p> <p>14 organization of my report.</p> <p>15 So some of the questions were organized</p> <p>16 into what are the various risks of cancer, what are</p> <p>17 the -- what is the state of guidelines regarding</p> <p>18 screening for cancer, what are the various</p> <p>19 technologies that we use for screening cancer, what</p> <p>20 are the various risks that are involved in screening</p> <p>21 for cancer, what are the characteristics of various</p> <p>22 screening tests, like the sensitivity and</p> <p>23 specificity of those screening tests for cancer,</p> <p>24 what are -- what are -- I guess this falls under the</p> <p>25 guidelines for screening for cancer, but what are</p>	<p style="text-align: right;">Page 33</p> <p>1 want to know who you directed these questions to and</p> <p>2 who would be gathering the information to provide to</p> <p>3 you and if you knew if those people were physicians?</p> <p>4 MR. STOY: Objection to form.</p> <p>5 THE WITNESS: As I mentioned, I primarily</p> <p>6 dealt with the people that I named that I was</p> <p>7 interacting with at Analysis Group. There is likely</p> <p>8 a support team to help those people, but those</p> <p>9 people are very knowledgeable in healthcare, very</p> <p>10 knowledgeable in health policy and would interface,</p> <p>11 I think, well if there were a physician on the</p> <p>12 health policy question like a screening guideline.</p> <p>13 So I don't know if they were interfacing</p> <p>14 with any physicians at Analysis Group. They could</p> <p>15 have been.</p> <p>16 BY MR. MIGLIACCIO:</p> <p>17 Q. Got it.</p> <p>18 What -- what arrangements did you come to</p> <p>19 regarding your fee and -- and your fees in the --</p> <p>20 for the report?</p> <p>21 MR. STOY: Object to the form.</p> <p>22 THE WITNESS: Can you restate that</p> <p>23 question?</p> <p>24 BY MR. MIGLIACCIO:</p> <p>25 Q. I mean, do you have an arrangement with</p>

<p style="text-align: right;">Page 34</p> <p>1 respect to fees for -- for the report?</p> <p>2 A. Yes.</p> <p>3 Q. And what is that arrangement?</p> <p>4 A. The arrangement is that I am paid for my</p> <p>5 own time at a rate of \$850 an hour, as stated in my</p> <p>6 report. That is the arrangement that I have with</p> <p>7 the lawyers in this case.</p> <p>8 And I also am paid what's called</p> <p>9 attribution, which is a percentage of the fees that</p> <p>10 Analysis Group charges for the work in support of my</p> <p>11 work.</p> <p>12 Q. Got it.</p> <p>13 What is that percentage that you get for</p> <p>14 attribution?</p> <p>15 A. Is that in my report? I'm not sure --</p> <p>16 THE WITNESS: Is that privileged</p> <p>17 information or is that...</p> <p>18 MR. MIGLIACCIO: I don't think that's</p> <p>19 privileged. I mean, I can talk with Frank about it,</p> <p>20 but I think that directly goes to -- to what -- you</p> <p>21 know, what his compensation is.</p> <p>22 MR. STOY: Yeah, you --</p> <p>23 MR. MIGLIACCIO: Frank, I --</p> <p>24 MR. STOY: You can answer that question,</p> <p>25 Dr. Chan, if you know.</p>	<p style="text-align: right;">Page 36</p> <p>1 about that, but that's something that we can talk</p> <p>2 about off the record.</p> <p>3 MR. MIGLIACCIO: Sure.</p> <p>4 MR. STOY: Your request is noted.</p> <p>5 BY MR. MIGLIACCIO:</p> <p>6 Q. Do your hourly rate -- does your hourly</p> <p>7 rate change for deposition testimony, like do you</p> <p>8 have a day rate for this or is it just -- just an</p> <p>9 hourly rate?</p> <p>10 A. It's just the hourly rate.</p> <p>11 Q. Same rate.</p> <p>12 Trial testimony, different rate, same</p> <p>13 rate?</p> <p>14 A. I believe it's the same rate.</p> <p>15 Q. And file review, I mean, if -- do you</p> <p>16 have -- is that a separate rate or is that the same,</p> <p>17 too?</p> <p>18 A. Same rate for everything.</p> <p>19 Q. Okay. So like fair to say, then, that you</p> <p>20 only have this \$850-an-hour rate for whatever you</p> <p>21 do?</p> <p>22 A. Yes.</p> <p>23 Q. It's that simple. Okay. Got it.</p> <p>24 Have you billed anything -- let me --</p> <p>25 strike that.</p>
<p style="text-align: right;">Page 35</p> <p>1 THE WITNESS: Okay.</p> <p>2 20 percent.</p> <p>3 BY MR. MIGLIACCIO:</p> <p>4 Q. 20 percent.</p> <p>5 So that -- so you receive 20 percent of</p> <p>6 the fees that attribution -- that Analysis Group has</p> <p>7 billed and recovered for this report, too?</p> <p>8 A. Correct.</p> <p>9 Q. Got it.</p> <p>10 Is that reflected in a written agreement</p> <p>11 anywhere?</p> <p>12 A. That's reflected in an agreement that I</p> <p>13 have with the Analysis Group.</p> <p>14 Q. Do we have that agreement? I -- I don't</p> <p>15 recall seeing it.</p> <p>16 A. I don't know.</p> <p>17 MR. MIGLIACCIO: Frank, do you know?</p> <p>18 MR. STOY: I don't believe that is</p> <p>19 something that we've produced.</p> <p>20 MR. MIGLIACCIO: Okay. I'm going to just</p> <p>21 mark for the record that I'm -- you know, we do want</p> <p>22 to see it. Prefer to see it today, if possible, so</p> <p>23 we could -- you know, I think it's directly called</p> <p>24 for by the -- by the Rules and by our request.</p> <p>25 MR. STOY: All right. Well, I'm not sure</p>	<p style="text-align: right;">Page 37</p> <p>1 What percentage of your income, you know,</p> <p>2 would you say comes from -- from your expert work?</p> <p>3 MR. STOY: And you can answer that</p> <p>4 question but you don't have to answer -- you don't</p> <p>5 have to elaborate about, you know, what your income</p> <p>6 level is.</p> <p>7 MR. MIGLIACCIO: I'm not asking for that.</p> <p>8 Q. I'm -- yeah, I'm not asking you for that.</p> <p>9 I understand.</p> <p>10 A. Right. Right.</p> <p>11 I'm not sure I can kind of give you a</p> <p>12 precise figure here. I can maybe tell you the</p> <p>13 percent of my time that I spent, but you're asking</p> <p>14 the percent of my income.</p> <p>15 Q. Right. Right.</p> <p>16 You could tell -- tell me your time and --</p> <p>17 I mean, you can think about the income question. We</p> <p>18 can come back to it later. I understand it's -- you</p> <p>19 might have to do some mental --</p> <p>20 A. Right. Yeah.</p> <p>21 Q. -- mental arithmetic.</p> <p>22 A. I'm afraid that if I answer the income</p> <p>23 question, you're going to back out my income.</p> <p>24 Q. I don't intend to back out your income. I</p> <p>25 just want to get -- I'm not trying to -- and this --</p>

<p style="text-align: right;">Page 38</p> <p>1 I mean, I'm not trying to get at sensitive personal 2 information here. That's not my goal. 3 I just want to see, you know, what you do 4 in terms of, you know, is this a big part of -- of 5 your life or is it a small part? That's what I'm 6 trying to drive at. 7 A. Uh-huh. In terms of the hours that I 8 spend on my work, it's -- I would say it's a 9 relatively small part of my life. 10 If you're -- if you're asking whether this 11 is a small part of my life or a big part of my life, 12 I would say it's -- you know, I spend most of my 13 hours not working on litigation consulting. 14 Q. If I could -- could you ballpark a 15 percentage of the percentage of your time spent on 16 litigation consulting? 17 A. I'm sorry, say that again. 18 Q. Could -- could you ballpark a percentage 19 of the time you spend working on litigation 20 consulting? 21 A. Ballpark would be less than 20 percent. 22 Q. Got it. Got it. 23 I want to ask you some questions about 24 your -- your background. 25 I know, you know, you're a physician and</p>	<p style="text-align: right;">Page 40</p> <p>1 in the Ph.D. in economics at MIT after finishing my 2 residency in internal medicine. I finished my Ph.D. 3 in economics in 2013. 4 And then I had my first job as a faculty 5 here at Stanford. 6 Q. Got it. 7 So you started -- the -- the -- it sounds 8 like you -- you took time -- did you take time off 9 from medical school? Do I have that straight or -- 10 A. It was a leave of absence from medical 11 school. I would say about a third of my class took 12 some form of leave of absence to do some type of 13 research work or some type of fellowship in the 14 middle of med school and mine was to do economics 15 and health policy. 16 Q. Got it. 17 I didn't mean that in a pejorative way to 18 say "time off." I understand a leave of absence. 19 So -- and that's when you -- you became a 20 Marshall Scholar and went to -- to get those 21 degrees? 22 A. Correct. 23 Q. Got it. 24 And I think I have your CV up here now. 25 We can --</p>
<p style="text-align: right;">Page 39</p> <p>1 an economist, you know, and you have multiple 2 degrees. I -- you know, can you walk me through 3 your educational history and kind of what -- just 4 for starters. 5 A. Sure. 6 Would you like to refer to the CV or would 7 you like me to just -- 8 Q. We can pull -- you can go -- you can just 9 go and -- because I can try to get the CV up. I'm 10 sure I'll be able to, you know, once I figure out 11 this technology. I'm not trying to hide it from 12 you. 13 A. Sure. 14 My first degree that I post -- after 15 undergrad that I enrolled in was a medical degree at 16 UCLA. In the middle of that medical degree, I 17 became quite interested in health policy and health 18 economics and I took two years off where I was a 19 Marshall Scholar in England and had two master's 20 degrees in health policy and health economics. 21 After coming back from that, I completed 22 medical school and started my residency program at 23 Brigham and Women's Hospital in Boston. 24 And I kind of knew that I wanted to do a 25 Ph.D. when I came back from England and I enrolled</p>	<p style="text-align: right;">Page 41</p> <p>1 MR. MIGLIACCIO: I'd like to mark the 2 report and the attachments as Exhibit 2. 3 (Whereupon, Chan Exhibit 2 was marked for 4 identification.) 5 BY MR. MIGLIACCIO: 6 Q. And I think it's up there now. 7 A. Okay. Yeah, I see it. 8 Q. Yeah. I see -- I think your CV is 9 Appendix A. 10 A. Right. 11 Q. Yeah. 12 A. Great. 13 Q. Yeah. Great. 14 You -- I see. So that -- and that -- I 15 see. So you -- you start -- did you start medical 16 school directly after college? 17 A. Correct. 18 Q. Okay. And then you took the leave of 19 absence to become a Marshall Scholar to go and get 20 these other degrees and then finish medical school? 21 A. Correct. 22 Q. Got it. 23 And then later, obtained your Ph.D. from 24 MIT? 25 A. Correct.</p>

<p style="text-align: right;">Page 42</p> <p>1 Q. Got it.</p> <p>2 What did you -- in terms of your career as</p> <p>3 a physician, could you walk me through that?</p> <p>4 A. Sure.</p> <p>5 My residency was in internal medicine.</p> <p>6 This was at Brigham and Women's Hospital where I</p> <p>7 spent quite a bit of time in primary care. They</p> <p>8 have a primary care track at -- in this residency</p> <p>9 program. So I spent quite a bit in outpatient</p> <p>10 medicine. But the average -- still the average</p> <p>11 residency program is predominantly inpatient</p> <p>12 medicine, but I spent a little bit more time than</p> <p>13 the average resident in primary care.</p> <p>14 I finished that residency in 2008 and</p> <p>15 that's when I started the Ph.D. program in</p> <p>16 economics.</p> <p>17 During the first year of the Ph.D.</p> <p>18 program, I did not have a steady clinical job. I --</p> <p>19 I worked as a physician as a -- what's called a --</p> <p>20 well, it's a moonlighting position where you would</p> <p>21 kind of put in -- I probably worked maybe 20 nights</p> <p>22 that year or 30 nights that year where you kind of</p> <p>23 worked at a hospital, at the Brigham in particular,</p> <p>24 and I admitted patients at that hospital.</p> <p>25 And then in my second year of the Ph.D.</p>	<p style="text-align: right;">Page 44</p> <p>1 jobs.</p> <p>2 And I had my first kind of staff job where</p> <p>3 I was educating residents at Beth Israel Deaconess</p> <p>4 Medical Center. This was in 2010, starting in</p> <p>5 November of 2010. I had that job all the way until</p> <p>6 I finished my Ph.D. in June of 2013.</p> <p>7 And then after that I came here to</p> <p>8 Palo Alto for an academic appointment at Stanford</p> <p>9 where I was a staff physician in internal medicine</p> <p>10 at the Palo Alto Veterans Affairs Health Care</p> <p>11 System.</p> <p>12 Q. Got it.</p> <p>13 So that first position at Brigham --</p> <p>14 Brigham and Women's, you said that that had a</p> <p>15 significant part of outpatient work? Did I have</p> <p>16 that straight?</p> <p>17 A. It had as much -- had more outpatient</p> <p>18 exposure than the average internal medicine</p> <p>19 residency program.</p> <p>20 Q. And how do you characterize that or</p> <p>21 quantify that?</p> <p>22 A. You can quantify it by the number of</p> <p>23 outpatient weeks that we have. So the typical</p> <p>24 internal medicine residency is structured in terms</p> <p>25 of rotations. You spend some rotations on various</p>
<p style="text-align: right;">Page 43</p> <p>1 program, I had my first clinical job as an attending</p> <p>2 physician at Beth Israel Deaconess Medical Center,</p> <p>3 which you see there.</p> <p>4 Actually, strike that.</p> <p>5 That -- that was actually in the -- near</p> <p>6 the beginning of the third year of my Ph.D. so I</p> <p>7 think I continued to do moonlight -- you can see my</p> <p>8 appointments at hospitals and affiliated</p> <p>9 institutions on my CV.</p> <p>10 Q. Where -- can you just tell me that page</p> <p>11 that is?</p> <p>12 A. This is A -- A-2.</p> <p>13 Q. A-2. Okay.</p> <p>14 A. Yeah, so you could see that...</p> <p>15 Q. Yeah.</p> <p>16 A. Right.</p> <p>17 So I had two positions. I had two</p> <p>18 positions before I was a staff physician at Beth</p> <p>19 Israel Deaconess Medical Center. I was a staff</p> <p>20 physician at Brigham and Women's Hospital, but my</p> <p>21 job there was mainly a moonlighting position.</p> <p>22 And I also later that year, in 2008, was a</p> <p>23 staff physician at McLean Hospital, which is a</p> <p>24 hospital in the Massachusetts General Physicians</p> <p>25 Organization. Both of those jobs were moonlighting</p>	<p style="text-align: right;">Page 45</p> <p>1 inpatient wards. You spend some rotations in the</p> <p>2 emergency department, and you spend some rotation</p> <p>3 doing outpatient care. And this residency program</p> <p>4 that I did had more weeks on inpatient care than the</p> <p>5 typical residency program.</p> <p>6 Q. Got it.</p> <p>7 And did that change at some point where</p> <p>8 you ended up spending more time like as typical</p> <p>9 doing inpatient?</p> <p>10 A. Yes. I -- so after residency you have to</p> <p>11 choose what type of doctor you want to be. You</p> <p>12 could either go on to subspecialty fellowship and</p> <p>13 become, you know, say, a cardiologist or infectious</p> <p>14 disease doctor or you can remain within general</p> <p>15 medicine.</p> <p>16 And within general medicine there are</p> <p>17 generally two types of jobs you could have. One is</p> <p>18 an outpatient job so you spend a hundred -- almost a</p> <p>19 hundred percent of your time as an outpatient</p> <p>20 doctor, increasingly so in the way medicine is</p> <p>21 organized right now.</p> <p>22 Or you could be an inpatient doctor and</p> <p>23 spend close to a hundred percent of your time</p> <p>24 clinically as an inpatient doctor. And I chose the</p> <p>25 latter. So I'm what's called a hospitalist.</p>

<p style="text-align: right;">Page 46</p> <p>1 Q. Hospitalist. Got it. Got it. 2 Did you have any -- as a hospitalist, do 3 you have any specialties or is that -- hospitalist 4 is like a generalist; is that fair? 5 A. Yes, a hospitalist by definition is a 6 general internist who does not have a subspecialty. 7 Q. Okay. 8 A. So internal medicine is their specialty 9 and they have no subspecialty. 10 Q. Do you have any areas of interest takeaway 11 like a formal subspecialty? Do you have any areas 12 of interest? Do hospitalists have that? 13 A. No. Hospitalists are quite general. We 14 see a variety of patients in the inpatient setting. 15 At Palo Alto VA, I see patients who are 16 general medicine patients. I see oncology patients. 17 I see cardiology patients. A wide variety of 18 patients who require hospitalization. 19 Q. Got it. 20 And you've been at Palo Alto VA from 2013 21 to the present? 22 A. Correct. 23 Q. How -- how much time do you -- or have you 24 spent there on average, you know, in that period? 25 A. Right. I spend four weeks a year since I</p>	<p style="text-align: right;">Page 48</p> <p>1 A. Yeah, it's determined by how the 2 hospitalists group decides to schedule rotations. 3 Before I believe this last year, or the last two 4 years, the rotations were two-week blocks. So I 5 generally would work in two two-week blocks every 6 year. 7 Starting about a year or two ago, the 8 group decided to change it so that people would 9 generally work in one-week blocks. And so now I 10 work four one-week blocks. 11 Q. Got it. Got it. 12 And has that been the same like from 2013 13 to the present? 14 A. It has either been one-week blocks or 15 two-week blocks since 2013. 16 Q. Yeah. Got it. 17 Four weeks total? 18 A. Four weeks total. 19 Q. Got it. Got it. 20 In your position in -- in Deaconess and 21 in -- the other hospitals back east, what was your 22 schedule there? 23 I mean, I -- that's kind of broad so 24 I'll -- I don't -- let's just start with Beth 25 Israel.</p>
<p style="text-align: right;">Page 47</p> <p>1 started there at -- in 2013. There are some 2 hospitalists at Palo Alto VA that are full time and 3 I think the full time -- I would have to check but 4 oftentimes the full time -- a full-time hospitalist 5 might see less than -- might be on the wards for 6 less than half of the weeks of the year. So there's 7 never a hospitalist that works all of the weeks of 8 the year. 9 It's quite an intense job, I would say, 10 and so it's not something like outpatient medicine 11 where in outpatient medicine you can be seeing 12 patients every week of the year. In hospital 13 medicine, oftentimes a full-time person is half the 14 weeks of the year. 15 And for an academic hospitalist like me 16 that does research in addition to being a 17 hospitalist you can have a range from four weeks a 18 year to, I would say, as much as seven weeks a year, 19 eight weeks a year, within that range. 20 Q. Got it. 21 Do you do those four weeks a year in a row 22 or do you split them up? 23 A. I split them up. 24 Q. Okay. What is the period -- like the 25 split period that you take? Is it a week or --</p>	<p style="text-align: right;">Page 49</p> <p>1 A. Beth Israel Deaconess, I think my -- I 2 don't know a hundred percent sure, but I believe my 3 schedule was six weeks a year back there. And that 4 is a reflection of just the different hospitals have 5 different kind of norms in terms of what is the 6 number of weeks that academic physicians will work. 7 And so, as I mentioned, six weeks a year is kind of 8 within the range. 9 Q. Got it. 10 What -- and what type of people would 11 you -- what would -- how would you describe the 12 patient population, you know, at Beth Israel 13 Deaconess that you saw? 14 A. It was a fairly general patient 15 population. I would see a number of different -- 16 just the same as in Palo Alto VA, I would see 17 patients with a wide variety of internal medicine 18 complaints ranging from infectious disease to renal 19 to, you know, pulmonology, cardiology, oncology, 20 gastroenterology. 21 There -- there would be a number of 22 different inpatient conditions, that is typical of a 23 hospital medicine practice, that I would see there 24 at Beth Israel Deaconess Medical Center. 25 Q. Okay. Would you say there's a difference</p>

<p>Page 50</p> <p>1 at the -- at a VA hospital, like, is the patient 2 population any different than at Beth Israel? 3 A. The patient population at the VA is 4 predominantly male still. I would say it's 5 90 percent -- my patients are 90 percent male. At 6 Beth Israel Deaconess, we did not have that. You 7 know, the most obvious kind of structural difference 8 is that the VA sees veterans and most veterans are 9 male. 10 You will also have veterans that tend to 11 be linked to certain wars. So there's veterans of 12 the Vietnam era or veterans of kind of more recent, 13 Iraq and Afghanistan era. So you'll have the age of 14 the veterans kind of coming in waves that are 15 related to wars as opposed to Beth Israel Deaconess 16 we didn't have them. 17 Q. Got it. 18 So you see waves or bands of -- of age 19 ranges? 20 A. Correct. 21 Q. Got it. 22 The moonlighting job, can you tell me a 23 little bit more about what -- what that was? I 24 mean, I -- I don't mean to say "job." The 25 moonlighting schedule, is that better? Schedule?</p> <p>Page 51</p> <p>1 A. Sure. 2 Q. Yeah. 3 A. That was much more -- that was less -- 4 that was a flexible -- the reason people have 5 moonlighting jobs is to allow for flexibility. You 6 don't necessarily commit to a schedule a whole year 7 in advance, which is what I do now. Nowadays, I 8 will say, what years I'm -- I will know which weeks 9 I'm going to be working a whole year in advance. 10 For the moonlighting job, generally, the 11 way that it works is that people sign up for shifts 12 and this signing up of shifts can happen maybe like 13 two weeks in advance or maybe a month in advance. 14 And generally, these would be for one-night shifts 15 or a shift maybe kind of lasting until the day but 16 not a whole week-shift as what I kind of currently 17 work on. 18 Q. Got it. Got it. 19 And did your duties vary as a -- you know, 20 a hospitalist in these -- across these positions or 21 were they similar, would you say? 22 A. I would say they were quite similar 23 despite the fact that they're on different coasts. 24 Medicine I think is quite homogenous across 25 different medical centers.</p>	<p>Page 52</p> <p>1 In Palo Alto VA, I solely work with 2 residents, whereas in Beth Israel Deaconess, there 3 was -- there were two different campuses, one in 4 which I worked with residents, the other in which I 5 kind of was more like a community doctor role where 6 I saw the patients alone and interacted directly 7 with the patients and the nurse and didn't have this 8 other group of doctors assisting me as I do now a 9 hundred percent. That would be kind of the only 10 difference. But in general, the jobs were quite 11 similar. 12 Q. Got it. 13 What -- I think you've answered this, but 14 you don't have any specific oncology expertise, is 15 that fair, as a generalist? 16 MR. STOY: Object to the form. 17 THE WITNESS: I would say that I don't 18 have oncology subspecialty training. I do see 19 oncology patients because oncology patients often 20 have medical problems, general medical problems. 21 They get infected. They can get quite sick 22 ultimately in ways that a general internist will 23 deal with. 24 I do not make decisions in terms of 25 initiation of chemotherapy so if there is such a</p> <p>Page 53</p> <p>1 decision like that, I will work in consultation with 2 an oncologist. 3 The way that hospital medicine works is 4 that if it's a general medicine problem on an 5 oncology patient I can -- I have -- you know, I 6 handle that on my own. Sometimes it makes sense to 7 consult subspecialty physicians like cardiologist, 8 oncologist to help in the management of a patient. 9 BY MR. MIGLIACCIO: 10 Q. Got it. 11 And when you consult with an oncologist or 12 cardiologist to help with the management of a 13 patient who requires that, like how does the 14 relationship work between the -- the hospitalist and 15 that specialist? 16 A. It's a collegial relationship. I will ask 17 them to see the patient and render -- I think to use 18 legal terms, render their opinions, and they will 19 provide that information to me and ultimately -- it 20 depends on which hospital it is. 21 At the Palo Alto VA, I'm the -- what's 22 called the attending of record. So I have -- 23 ultimately the decision lies with me. So if -- you 24 know, if you had to point to one decisionmaker, it 25 would be me.</p>
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<p style="text-align: right;">Page 54</p> <p>1 That said, I'm going to very much consider 2 what the oncologist or the cardiologist or the 3 nephrologist, you know, the various consultants will 4 kind of provide me. And that information will very 5 much influence what I do. 6 Q. And these are for -- I think you said, and 7 I don't want to put words in your mouth, like this 8 is for a general medicine problems if the patient 9 has such a problem? 10 A. Can you state that again? 11 Q. You're consulting with a specialist if 12 that patient is in your care and they have a problem 13 that's not, you know, an oncology problem or a 14 cardiology problem or -- and -- am I getting this 15 wrong? 16 A. If it's a general medicine problem, then 17 it's fully within my domain to -- 18 Q. Yeah. 19 A. -- make a decision without any input from 20 a consultant. 21 Q. Okay. 22 A. If there is some type of specialized 23 knowledge beyond general medicine that would be 24 helpful in making my decision, then I might consult 25 them.</p>	<p style="text-align: right;">Page 56</p> <p>1 the hospital for pneumonia. That patient I won't 2 consult an oncologist generally. 3 There are other patients where we need to 4 make a decision about changing a chemotherapy 5 regimen. Then I will consult the oncologist. But 6 while the patient is in the hospital, the patient is 7 under my care and the oncologist is secondary. 8 Q. Okay. I think I understand. 9 If somebody -- for purposes of diagnosis 10 of a cancer and initial treatment plan, that would 11 be done by an oncologist? 12 A. For purposes of the treatment plan, like 13 the chemotherapy plan, that would be primarily done 14 by the oncologist. They would have certainly the 15 biggest say in that, with the caveat that the 16 general internist and maybe even the primary care 17 doctor, you're going to try to take the patient's 18 wishes or the patient's preferences into 19 consideration. You have to also consider other 20 comorbidities that the patient has. 21 So it's not purely an oncology decision. 22 It's a holistic decision that's made by generalists 23 and oncologists. 24 With respect to diagnosing cancers, I 25 think that often happens by internist, general</p>
<p style="text-align: right;">Page 55</p> <p>1 The way that it works at Palo Alto VA is 2 that there is no oncology ward where an oncologist 3 is the attending of record so that means all 4 oncology patients will kind of, quote/unquote, 5 belong to me. I am the attending of record for all 6 oncology patients, and I'll be making -- I'm the 7 person -- I'm the single decisionmaker if you were 8 to name one. 9 If there is a specialized question that I 10 would like input on such as a chemotherapy regimen 11 or, you know, something that's specifically about 12 their cancer, then I will generally consult an 13 oncologist. 14 Q. Got it. 15 And so you, as -- as -- in your position 16 at Palo Alto, then, if you have a patient who 17 presents with a cancer, that patient will be under 18 your care or will it -- or -- or jointly under your 19 care and jointly under the care of an oncologist? 20 A. It's hard to define what we mean by 21 "jointly." I would say that some oncology patients 22 we will never consult an oncologist. Some, if their 23 condition is purely medical, for example, you might 24 be an oncology patient to have, like, cancer, you 25 are being treated for this cancer, but you come to</p>	<p style="text-align: right;">Page 57</p> <p>1 internists as opposed to oncologist. Oftentimes the 2 cancer is diagnosed initially by a patient who comes 3 in with a complaint and we find cancer. Then after 4 we find cancer, we refer the patient to an 5 oncologist. So I would say the diagnosis of cancer 6 often happens with generalists. 7 Q. Have you diagnosed cancer before? 8 A. Yes. 9 Q. What -- what types of cancer have you 10 diagnosed? 11 A. Almost all types of cancers, I would say. 12 Q. What is metastatic cancer? 13 A. Metastatic. 14 Q. Metastatic, sorry. 15 A. That is a cancer that has spread to a 16 distant site. 17 Q. Is that type of cancer frequently 18 incurable? 19 MR. STOY: Object to the form. 20 THE WITNESS: I think it depends on the 21 type of cancer. There are some cancers such as 22 leukemia that are widespread. They are quite 23 treatable and quite curable. 24 BY MR. MIGLIACCIO: 25 Q. What are the benefits of finding a cancer</p>

<p style="text-align: right;">Page 58</p> <p>1 early?</p> <p>2 MR. STOY: Object to the form.</p> <p>3 Go ahead.</p> <p>4 THE WITNESS: I think this -- yeah, this</p> <p>5 gets to my report where there -- there could be</p> <p>6 benefits and risks of pursuing a cancer early. When</p> <p>7 you have an earlier cancer, it might be more</p> <p>8 amenable to treatment in a sense that there's</p> <p>9 less -- it has to -- I mean, yeah.</p> <p>10 The cancer needs to be detectable, like if</p> <p>11 the cancer is small enough where it's not</p> <p>12 detectable, then you wouldn't generally operate on</p> <p>13 it to remove it. You also wouldn't give</p> <p>14 chemotherapy.</p> <p>15 So there is, I think, still like an</p> <p>16 optimal time to be thinking about when to detect</p> <p>17 cancer. You don't want to be detecting cancer or</p> <p>18 even try to detect cancer when it's just a few --</p> <p>19 few cells. That would be infeasible.</p> <p>20 And there -- there is also if -- you know,</p> <p>21 the disease burden from cancer is quite advanced and</p> <p>22 for certain cancers, if it's metastatic, it becomes</p> <p>23 harder to -- the patient's life expectancy from</p> <p>24 there is -- is lower and the odds of you</p> <p>25 definitively sending that cancer into remission are</p>	<p style="text-align: right;">Page 60</p> <p>1 a lot of considerations here.</p> <p>2 BY MR. MIGLIACCIO:</p> <p>3 Q. And I'm only asking about the benefits,</p> <p>4 not the costs. I understand that -- that, you know,</p> <p>5 and in your report you lay out your opinions. I</p> <p>6 understand that, you know, but I'm not asking you</p> <p>7 about the downsides. I'm only asking you about the</p> <p>8 upsides.</p> <p>9 MR. STOY: Same objection.</p> <p>10 Go ahead.</p> <p>11 THE WITNESS: Could you state that</p> <p>12 question again?</p> <p>13 BY MR. MIGLIACCIO:</p> <p>14 Q. Yeah.</p> <p>15 What -- what are the benefits, you know,</p> <p>16 not -- not the drawbacks, not the costs, what are</p> <p>17 the benefits of detecting a cancer before it becomes</p> <p>18 metastatic?</p> <p>19 A. It's really kind of hard for me to speak</p> <p>20 generally on this. I think there are a number of</p> <p>21 different types of cancer. This might differ across</p> <p>22 different types of cancer.</p> <p>23 Q. Sure. We can -- we can go through -- we</p> <p>24 can go cancer by cancer.</p> <p>25 Let's talk about, like, let's say,</p>
<p style="text-align: right;">Page 59</p> <p>1 lower as well.</p> <p>2 So it's -- it's -- it's a balance. There</p> <p>3 are -- there are risks and benefits of pursuing a</p> <p>4 cancer early, and I think there is probable an</p> <p>5 optimal time to be thinking about whether somebody</p> <p>6 has cancer.</p> <p>7 MR. STOY: Nick, I don't want to interrupt</p> <p>8 you. If you've got -- you know, if this isn't a</p> <p>9 good spot, but we have been going for a little over</p> <p>10 an hour so, you know, whenever is a good time to</p> <p>11 take a break.</p> <p>12 MR. MIGLIACCIO: Sure. Why don't we just</p> <p>13 take like five more minutes and then we can take a</p> <p>14 break, if that's all right.</p> <p>15 MR. STOY: That's fine.</p> <p>16 MR. MIGLIACCIO: I know -- and even on the</p> <p>17 East Coast here we're close to lunch but we'll sort</p> <p>18 that.</p> <p>19 Q. Can we agree that it's generally</p> <p>20 preferable to detect a cancer before it becomes</p> <p>21 metastatic?</p> <p>22 MR. STOY: Object to the form of the</p> <p>23 question.</p> <p>24 Go ahead.</p> <p>25 THE WITNESS: Yeah, I think there are just</p>	<p style="text-align: right;">Page 61</p> <p>1 prostate cancer.</p> <p>2 A. Uh-huh.</p> <p>3 Q. Which is one example.</p> <p>4 A. Okay.</p> <p>5 Q. What -- what would be the benefits of --</p> <p>6 of catching that before it becomes metastatic?</p> <p>7 A. Even then, even if you focus on a specific</p> <p>8 type of cancer, I think it depends on things that</p> <p>9 are outside of cancer.</p> <p>10 Potentially, if -- if -- you know, again,</p> <p>11 this is a little bit hypothetical, but, you know, if</p> <p>12 you have a patient with metastatic -- as I</p> <p>13 mentioned, if you have a patient with metastatic</p> <p>14 prostate cancer, it becomes harder to treat.</p> <p>15 And this is kind of a very general</p> <p>16 statement. As I mentioned, I am not, you know, an</p> <p>17 oncologist.</p> <p>18 When somebody comes into the hospital and</p> <p>19 has a medical problem, I'm generally treating that</p> <p>20 medical problem. I'm not making chemotherapy</p> <p>21 decisions, so -- and I'm also not following cancer</p> <p>22 patients long-term as well. I'm not directing --</p> <p>23 chemotherapy is usually an outpatient regimen.</p> <p>24 So, you know, I can speak to this in</p> <p>25 general terms, but, you know, I think that there are</p>

<p style="text-align: right;">Page 62</p> <p>1 just so many different factors to consider in -- 2 there are -- it's -- it's a complicated decision 3 that requires, you know, more than just like an 4 inpatient hospitalization, which is what I deal 5 with. 6 Q. Got it. 7 But we can agree that it's easier to 8 treat, then, before it becomes metastatic, a 9 prostate cancer? 10 MR. STOY: Object to the form. 11 THE WITNESS: Again, it depends, but I 12 would say that in many cases, in many cases, it is 13 treating a cancer that has not metastasized, or once 14 a cancer has metastasized, you would need more 15 systemic agents like chemotherapy as opposed to 16 surgery so it rules out certain therapeutic options. 17 And I can at least say that. 18 MR. MIGLIACCIO: Why don't we -- we can 19 take a break now, a quick break, maybe just ten 20 minutes or so. I know we need to figure out what 21 we're going to eat here. 22 MR. STOY: Oh, no, that -- that's fine. 23 I'm more worried about Dr. Chan's lunch and he's 24 still a little ways away. 25 MR. MIGLIACCIO: Yeah.</p>	<p style="text-align: right;">Page 64</p> <p>1 confidentiality order that governs any reports that 2 you might have authored in those cases. 3 So, you know, with that instruction to not 4 reveal any potentially confidential information 5 related to those other engagements, you can answer 6 the question to the extent you can. 7 THE WITNESS: Right. That leaves very 8 little room for me to discuss this. I think I can 9 say that you can see the parties involved in each of 10 these cases, the dates of the case, and I was 11 retained as an expert on the defendants' side. I 12 think I can say that. 13 BY MR. MIGLIACCIO: 14 Q. Okay. For each of those three cases? 15 A. Correct. 16 Q. Okay. And those cases -- were those -- 17 these are not whistleblower cases, are they? Are 18 they -- were the cases themselves filed under seal? 19 A. I don't think they're whistleblower cases. 20 Q. Okay. Can you tell me what you know about 21 the case, with the cases from what you know from the 22 publicly filed documents or complaints that were 23 filed in these cases? 24 A. Are the complaints public? Can I -- are 25 we certain that the complaints are public?</p>
<p style="text-align: right;">Page 63</p> <p>1 MR. STOY: So let's -- 2 MR. MIGLIACCIO: Right. 3 MR. STOY: Let's come back at 12:10, does 4 that work, 12:10 Eastern time? 5 THE VIDEOGRAPHER: All right. We're off 6 the record at 9:01 a.m. 7 (Whereupon, a brief recess was taken.) 8 THE VIDEOGRAPHER: We are back on the 9 record. The time is 9:15 a.m. Pacific time. 10 BY MR. MIGLIACCIO: 11 Q. Okay. All right. 12 Dr. Chan, I want to ask you a few 13 questions about your prior -- the prior reports and 14 opinions or deposition testimony that you offered 15 in -- I think it looks like three other cases that 16 are listed on your CV. I am on -- looking at it 17 right now, it looks like it's Appendix B. Okay. 18 Can you tell me about those cases? You 19 can start with just -- just from the top. 20 A. I don't know how much I can reveal. 21 MR. STOY: Yeah, before you -- before you 22 answer, Dr. Chan, I'll place an objection to the 23 form of the question, and I'll also just caution 24 you, I'm aware that there are protective orders in 25 place in those cases and I believe that there's a</p>	<p style="text-align: right;">Page 65</p> <p>1 Q. Well, that's -- that's why I asked if they 2 were -- if they were filed under seal and that's, 3 you know, what I'm trying to find out. They don't 4 appear to me to be whistleblower cases. They appear 5 to be -- 6 MR. STOY: Yeah, again, I'll just -- I'll 7 put this -- I'll reference my prior instruction and 8 just say, I mean, I think it's okay to talk about 9 the case generally at a high level but just not to 10 reveal anything that, you know, would potentially be 11 confidential. And if you -- if you're not able to 12 answer the question with that instruction, then so 13 be it. 14 But I just wanted to place that on the 15 record. 16 THE WITNESS: Frank, would you instruct me 17 to -- because I just don't know the legal -- the 18 legal details, whether this is the -- the complaints 19 are under seal or not. Am I allowed to discuss 20 the... 21 MR. STOY: Yeah, I don't -- I don't know 22 if -- Nick, if these complaints were filed under 23 seal or -- or what is confidential or what isn't. I 24 just know that there are confidentiality orders in 25 place and --</p>

<p style="text-align: right;">Page 66</p> <p>1 MR. MIGLIACCIO: Uh-huh.</p> <p>2 MR. STOY: -- you know, aspects of his</p> <p>3 report and testimony would be confidential.</p> <p>4 That is the limit of my knowledge so</p> <p>5 that's why I put the instruction that I did on the</p> <p>6 record.</p> <p>7 MR. MIGLIACCIO: Yeah, I understand that.</p> <p>8 And, you know, I do know we asked for this</p> <p>9 information, these transcripts, and I think you</p> <p>10 objected to providing them.</p> <p>11 I -- I think, you know, you could tell us</p> <p>12 the general subject matter of the case. I don't</p> <p>13 think you would be breaching any confidentiality.</p> <p>14 That -- that would be my request, that you tell us.</p> <p>15 MR. STOY: Yeah, I mean, I think he can</p> <p>16 answer a question like, you know, what is -- what's</p> <p>17 the product that was at issue in the case or</p> <p>18 something like that. But I just think, you know,</p> <p>19 it's going to depend on the question. And if the</p> <p>20 question is a really broad one, then it's going to</p> <p>21 be difficult for Dr. Chan to be able to provide an</p> <p>22 answer.</p> <p>23 THE WITNESS: And I would only want to</p> <p>24 reveal what's public information because I wouldn't</p> <p>25 want to divulge anything that's under confidential</p>	<p style="text-align: right;">Page 68</p> <p>1 Q. Okay. These -- these are all -- these</p> <p>2 were deposition -- these aren't trial testimony,</p> <p>3 this is all deposition testimony?</p> <p>4 A. Correct.</p> <p>5 Q. Do you know -- and you were retained by</p> <p>6 the defendants in these respective -- these three</p> <p>7 cases?</p> <p>8 A. I was retained by Janssen Pharmaceuticals.</p> <p>9 There are multiple defendants in this case. And I</p> <p>10 was retained by one of the defendants, which is</p> <p>11 Janssen Pharmaceuticals.</p> <p>12 Q. Okay. Did you -- was your opinion -- did</p> <p>13 you rely upon your expertise as a medical doctor or</p> <p>14 as an economist in -- in offering your opinion?</p> <p>15 A. Both.</p> <p>16 MR. STOY: Object to the form.</p> <p>17 BY MR. MIGLIACCIO:</p> <p>18 Q. All right. Have you -- has your testimony</p> <p>19 been -- been challenged in any of these three cases?</p> <p>20 A. No.</p> <p>21 Q. Do you know what I mean when I say</p> <p>22 "challenged"?</p> <p>23 A. I'm not a legal expert. My understanding</p> <p>24 of your question is that there was a movement by the</p> <p>25 other side to strike my testimony or strike my</p>
<p style="text-align: right;">Page 67</p> <p>1 order. And I -- I just don't know what is under</p> <p>2 confidential order or not. Yeah, I mean...</p> <p>3 MR. STOY: Well, let's wait. I don't</p> <p>4 think there's a question pending right now,</p> <p>5 Dr. Chan, so let's wait and -- wait for a question.</p> <p>6 BY MR. MIGLIACCIO:</p> <p>7 Q. But I mean, there was -- I just wanted to</p> <p>8 know what the general subject matter of the cases</p> <p>9 are. You know, what -- what are the cases about.</p> <p>10 You can -- you can tell me what the product at issue</p> <p>11 is. That -- that's fine.</p> <p>12 What -- what is the product at issue?</p> <p>13 THE WITNESS: Is that okay, Frank?</p> <p>14 MR. STOY: Yeah, I think -- I think you</p> <p>15 can answer that question, if you know.</p> <p>16 THE WITNESS: Right.</p> <p>17 The -- the product at issue in all three</p> <p>18 of these cases are -- were products by Janssen</p> <p>19 pharmaceutical or Johnson & Johnson. They were two</p> <p>20 specific opioid products produced by Janssen</p> <p>21 Pharmaceuticals or Johnson & Johnson.</p> <p>22 BY MR. MIGLIACCIO:</p> <p>23 Q. Not Janssen, Johnson & Johnson?</p> <p>24 A. They're -- I think -- my understanding is</p> <p>25 that Janssen is a subsidiary of Johnson & Johnson.</p>	<p style="text-align: right;">Page 69</p> <p>1 expertise.</p> <p>2 Q. It's to exclude or strike it, yeah,</p> <p>3 that -- that's my question, right.</p> <p>4 A. Right.</p> <p>5 Q. Yeah. And so the answer to that was no?</p> <p>6 A. That's no.</p> <p>7 Q. Okay. Did your testimony include any</p> <p>8 opinion relating to healthcare spending or pricing?</p> <p>9 MR. STOY: Object to the form.</p> <p>10 You can answer that question.</p> <p>11 THE WITNESS: It's hard for me to answer</p> <p>12 that question. It related to healthcare spending.</p> <p>13 Not sure about pricing.</p> <p>14 BY MR. MIGLIACCIO:</p> <p>15 Q. Healthcare spending. Got it.</p> <p>16 And when were you retained in these cases,</p> <p>17 if you can recall?</p> <p>18 A. I believe my first contact was before the</p> <p>19 pandemic so that would mean sometime in 2020,</p> <p>20 earlier 2020.</p> <p>21 Q. And is your work being done in those cases</p> <p>22 also with the Analysis Group?</p> <p>23 A. Yes.</p> <p>24 Q. Okay. In all three of them?</p> <p>25 A. Yes.</p>

<p>Page 70</p> <p>1 Q. Okay. Do you have -- what is your 2 relationship with the Analysis Group? Are -- are 3 you a consultant? Are you an owner? Are you an 4 employee? Could you just shed some light on that? 5 MR. STOY: Object to the form. 6 THE WITNESS: As I mentioned, I have a -- 7 an agreement with the Analysis Group that is -- 8 is -- basically allows me to use their services in 9 preparing work for or litigation consulting. I'm 10 not an employee of Analysis Group. I'm what's 11 called an affiliate of Analysis Group. And I 12 believe that just means that I have worked with them 13 in the past and I have a working relationship with 14 Analysis Group. 15 BY MR. MIGLIACCIO: 16 Q. Got it. 17 What was -- I think we -- we -- we 18 discussed this earlier, but what was the process 19 that you used -- I think you've -- you've answered 20 this. 21 Did your process for preparing your report 22 in this case differ for your process in preparing 23 any expert witness report in other cases? 24 MR. STOY: Object to the form. 25 THE WITNESS: Would you like to be more</p> <p>Page 71</p> <p>1 specific? 2 BY MR. MIGLIACCIO: 3 Q. I think you told me about your process 4 this morning. I'm not sure if you finished your 5 answer, if we finished that line of questioning. 6 But my question is, in the way that you 7 prepared this report, was this -- the way you 8 prepared this report, was it any different from -- 9 from what you've done in -- in other cases, 10 including these three that we just looked at? 11 MR. STOY: Object to the form. 12 You can answer. 13 THE WITNESS: Different from what I 14 described earlier. So I think you are referring to 15 my general process of reading the complaint, 16 thinking about the question, identifying lines of 17 inquiry that I would like more information or 18 analyses. 19 Are you referring -- if you're referring 20 to that, then that is my general process of thinking 21 through my opinions in a case of litigation 22 consulting. 23 BY MR. MIGLIACCIO: 24 Q. Have you -- other than these three 25 reports -- or rather, prior testimony, have you</p>	<p>Page 72</p> <p>1 offered opinions in any other litigation? 2 A. No. 3 Q. So -- so these three that you've been 4 deposed in that are listed on Appendix B, and this 5 case, this is the fourth case in total that you have 6 been retained for and offered expert opinions or -- 7 or testimony? 8 I'm not asking for questions about -- I'm 9 not asking for any cases where you may be a 10 consulting expert. I'm asking, you know, where 11 you've been disclosed and provided opinions or 12 deposition testimony. 13 A. And could you clarify to me what you mean 14 by provided expert opinions? Is this -- is this a 15 specific term meaning... 16 Q. A report, like a report. 17 A. A report. Okay. 18 Q. Yeah. 19 A. Thank you. 20 MR. STOY: Dr. Chan, my understanding is 21 he's limiting his question to cases where you've 22 been disclosed as a testifying expert, like in this 23 case, not any case that you might have been retained 24 as a consultant. 25 THE WITNESS: Okay.</p> <p>Page 73</p> <p>1 So the answer is yes. These -- these are 2 the only cases that I have been disclosed as an 3 expert. 4 BY MR. MIGLIACCIO: 5 Q. Got it. 6 And -- and -- and the first one looks 7 like -- I mean, you've just started this, you've 8 just started working as a disclosed expert with 9 these four cases, including these three? 10 A. By "just started working," you can see the 11 dates here -- 12 Q. Right. 13 A. -- is that what you mean? 14 Q. Yeah, that -- that's right. I mean, so 15 you -- there's not an earlier part of your career 16 where you provided expert testimony or expert 17 reports in other cases? 18 A. Correct. 19 Q. Okay. Got it. 20 I have -- in your report here you have a 21 list of materials relied upon. Looks like that's 22 exhibit -- it's just Appendix C of your report. 23 Do you have that up there? 24 A. Yes. 25 Q. So you looked at the Consolidated Third</p>
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<p style="text-align: right;">Page 74</p> <p>1 Amended Medical Monitoring Class Action Complaint, 2 Plaintiffs' Memorandum of Law in support of their 3 motion for class certification, and the Third 4 Amended Consolidated Economic Loss Class Action 5 Complaint. 6 A. Correct. 7 Q. And I think you testified to this earlier 8 that you looked at Dr. Conti, Dr. Kaplan, and 9 Dr. Song's reports. 10 You also, I see here, looked at the report 11 of Dr. Panigrahy; is that right? 12 A. I believe so, but I don't particularly 13 remember much about that report. 14 Q. Okay. And then are you aware that -- did 15 you ask to see any other expert reports? 16 A. No. 17 Q. No. 18 Did you -- are you aware that the 19 plaintiffs had put forward general causation expert 20 reports in this case? 21 A. Not very aware that. 22 Q. Are you aware that there were reports by 23 Dr. Etminan, Dr. Hecht, and Dr. Lagana? 24 A. No, I don't know those names. 25 Q. Are you aware of Dr. Daniel Catenacci?</p>	<p style="text-align: right;">Page 76</p> <p>1 have various data listed, is that right, on the next 2 page? 3 A. Uh-huh. 4 Q. And I'm just going to refer you to the 5 "Medical Expenditure Panel Survey data." 6 Do you see that? 7 A. Yes. 8 Q. Who -- who gathered that data for you? 9 A. I directed the Analysis Group to gather 10 that data, those data. 11 Q. Who is your -- who did you interface with 12 with respect to getting that information? 13 A. Almost all of my calls with the Analysis 14 Group involved the people that I mentioned earlier. 15 All of them. Some of the calls did not include 16 Molly Frea. But almost all of the calls involved 17 the other four people that I named, Brian Ellman, 18 Frank Mortimer -- Richard Mortimer, Jessica Lu, and 19 Michaela Johnson. And I directed them as a group to 20 get those data. 21 Q. Got it. 22 I want to look at your -- were there any 23 conclusions that you reached that did not make it 24 into your final report? 25 A. No.</p>
<p style="text-align: right;">Page 75</p> <p>1 A. No, I don't know who that is. 2 Q. Dr. Janice Britt? 3 A. No. 4 Q. Have you ever heard of those names before? 5 A. I've never heard those names before. 6 Q. All right. What was your recollection -- 7 I mean, what is your recollection, as you sit here 8 today, of Dr. Panigrahy's report? 9 A. I don't have much of a recollection at 10 all, actually. I don't know who that person is. 11 I -- I might have seen that report, but I don't 12 remember anything about it. 13 Q. Do you recall anything about the 14 depositions of Judson -- I'm just -- it says, 15 "Depositions and Declarations." 16 A. Oh. 17 Q. And it looks like there are one, two, 18 three, four -- seven of them listed there. 19 A. Uh-huh. I know some of their medical 20 conditions. I know that they're specific named -- 21 named -- named plaintiffs and so I know -- I know 22 their -- as I mention in my report, I know some of 23 their medical conditions. 24 Q. Got it. 25 And then I see further below, "Data," you</p>	<p style="text-align: right;">Page 77</p> <p>1 Q. And let -- let's look at your -- the 2 invoices. I think I -- I will put -- pull those up 3 for you if we just bear with me for a moment. 4 Did I do it right? Okay. It should -- 5 they should pop up in a few minutes -- or a few 6 seconds. 7 Let me know when you can see them. 8 A. Yes, I can see them. 9 (Whereupon, Chan Exhibit 3 was marked for 10 identification. 11 BY MR. MIGLIACCIO: 12 Q. Okay. Great. 13 This is -- this is the invoice we were 14 provided with. 15 A. Uh-huh. 16 Q. And it's dated February 3rd, 2022. 17 A. Right. 18 Q. And it looks like it was "For professional 19 services rendered in connection with the above 20 referenced case for the period ending December 31, 21 2021." 22 A. Uh-huh. 23 Q. Are there any other invoices or did you 24 spend any other time on this report? 25 MR. STOY: Object to -- object to the</p>

<p style="text-align: right;">Page 78</p> <p>1 form. I think that's two different questions. 2 THE WITNESS: Okay. Yeah. 3 BY MR. MIGLIACCIO: 4 Q. Yeah. First, are there any other invoices 5 that haven't been -- 6 A. I have not yet submitted any other 7 invoices. 8 Q. Okay. Do you have -- do you have a plan 9 to submit another invoice? 10 A. Yes. 11 Q. Okay. And what would be included on that 12 invoice aside from today's deposition or in 13 preparation for the deposition? 14 A. I haven't prepared them yet. Those would 15 be invoices for the months of January and for the 16 month of February. 17 Q. Okay. How much time -- so your report 18 looks like it's dated January 12th, right? 19 A. Right. 20 Q. Could you estimate how much time you spent 21 in the month of January on the report before it was 22 signed and submitted on the 12th? 23 A. Off the top of my head, no. I think it 24 was a significant amount of time given that we were 25 up against a deadline. But off the top of my head,</p>	<p style="text-align: right;">Page 80</p> <p>1 subsequently. Off the top of my head, I don't know 2 what Ph.D. he has, but it's likely -- I believe he's 3 an economist. 4 Q. Ellman, B. Ellman? 5 A. Brian Ellman, I think he has an MBA. I 6 don't remember exactly where the MBA is from. He's 7 an economist and he's a principal. 8 Q. M. Johnson? 9 A. Michaela Johnson, my understanding is a 10 manager is below the level of a partner but is quite 11 experienced, has quite a bit of industry experience 12 as well as consulting experience. She has an MBA 13 from MIT. 14 Q. I. Karagodsky? 15 A. I believe he was on maybe one call or two 16 calls. I don't know him as well. 17 Q. Do you know what qualifications he may 18 have? 19 A. I don't know in particular. 20 Q. Okay. 21 A. I believe it's all -- I would expect that 22 all to be on their website if I wanted to look it 23 up. 24 Q. Got it. 25 F. Balestrieri?</p>
<p style="text-align: right;">Page 79</p> <p>1 I can't tell you the number of hours. 2 Q. Got it. Got it. 3 So to -- to look, I'm looking at the 4 first -- or rather, the second page, page 2, and 5 there I think the people that you've referenced are 6 listed as professionals with their titles and their 7 hours and rates. 8 A. Right. 9 Q. Do you see that? 10 A. I do. 11 MR. STOY: Object to the form. 12 BY MR. MIGLIACCIO: 13 Q. Can you tell me, you know, Mortimer, 14 R. Mortimer, what background that person has in 15 terms of degrees or qualifications? 16 A. Richard Mortimer. I believe he has a 17 Ph.D. in economics from Berkeley. He's a principal, 18 which means a partner. I don't know the difference 19 between a managing principal and a principal, but I 20 think, broadly speaking, they're -- they're like 21 partners at -- at AG. 22 Q. Fink. S. Fink? 23 A. Stephen Fink is another partner. He was 24 involved -- I -- now I remember he was involved in 25 early discussions in the case but not very much</p>	<p style="text-align: right;">Page 81</p> <p>1 A. F. Balestrieri was not on most of the 2 call -- I don't remember that person being on calls. 3 Q. J. Bernard? 4 A. I don't remember that person being on 5 calls. 6 Q. And you don't know Balestrieri or Bernard, 7 their -- their qualifications? 8 A. No. 9 Q. J. Lu? 10 A. Jessica Lu. 11 Q. Yeah. 12 A. Was on almost all the calls. She has an 13 MBA from MIT. And she's a manager. 14 Q. S. Livingston? 15 A. I don't know who that person is. 16 Q. M. Frea? 17 A. Right. Molly Frea. She has a Ph.D. from 18 University of Pennsylvania. 19 Q. And did you work with her a lot on this? 20 A. I would say less than Jessica and 21 Michaela, Brian, and -- she was less present than 22 those four but she was present on a few of the 23 calls. 24 Q. A. Khan? 25 A. I don't remember working with that person.</p>

<p style="text-align: right;">Page 82</p> <p>1 Q. And N. Mwonga?</p> <p>2 A. I don't remember working with that person</p> <p>3 either.</p> <p>4 Q. T. Radtke?</p> <p>5 A. I don't remember working with that person.</p> <p>6 Q. Okay.</p> <p>7 I. Tibrewal?</p> <p>8 A. And I don't remember working with that</p> <p>9 person.</p> <p>10 Q. Got it.</p> <p>11 Were there any other people that you</p> <p>12 remember working with other than that -- that are --</p> <p>13 that are listed here?</p> <p>14 A. No.</p> <p>15 Q. Okay. Did you review this bill before it</p> <p>16 was submitted?</p> <p>17 A. I submitted my hours, but I don't review</p> <p>18 the hours of -- submitted by Analysis Group.</p> <p>19 Q. Got it. All right.</p> <p>20 I want to ask you some questions about the</p> <p>21 scope of your opinions here in this case.</p> <p>22 Were you -- or are you offering any</p> <p>23 opinions on epidemiology or general causation?</p> <p>24 A. What do you mean by "general causation"?</p> <p>25 Q. Are you offering an opinion whether the</p>	<p style="text-align: right;">Page 84</p> <p>1 to my opinion.</p> <p>2 BY MR. MIGLIACCIO:</p> <p>3 Q. And you're not offering that opinion</p> <p>4 specifically?</p> <p>5 A. No.</p> <p>6 Q. Okay. Fair to say you did not do anything</p> <p>7 to review the epidemiology in this case or</p> <p>8 investigate general causation?</p> <p>9 MR. STOY: Object to the form to the</p> <p>10 extent it misstates his testimony.</p> <p>11 Go ahead.</p> <p>12 THE WITNESS: I would say that I did</p> <p>13 not -- it's not a core opinion of mine to comment on</p> <p>14 general causation. Epidemiology is relevant in</p> <p>15 other ways, broadly speaking.</p> <p>16 When you consider epidemiology as the</p> <p>17 prevalence of other diseases or the characteristics</p> <p>18 of people that take valsartan versus the people that</p> <p>19 don't take valsartan, there are other elements of</p> <p>20 epidemiology that are important for my opinion.</p> <p>21 BY MR. MIGLIACCIO:</p> <p>22 Q. Let me -- let me give you more specific</p> <p>23 question.</p> <p>24 You didn't look at the question of -- you</p> <p>25 didn't look at epidemiology with respect to the</p>
<p style="text-align: right;">Page 83</p> <p>1 contaminated valsartan at issue in this case, it can</p> <p>2 cause cancer?</p> <p>3 A. I'm not rendering any opinions on whether</p> <p>4 valsartan with nitrosamine impurities can cause</p> <p>5 cancer.</p> <p>6 Q. Got it.</p> <p>7 I want to direct you to paragraph 44 of</p> <p>8 your -- of your report.</p> <p>9 A. Okay.</p> <p>10 Q. And what -- you state -- and -- "While</p> <p>11 NDMA and NDEA exposure may be perceived as a</p> <p>12 potential general cancer risk, it has not been</p> <p>13 demonstrated as a risk with respect to any specific</p> <p>14 type of cancer, nor has the presence of nitrosamines</p> <p>15 in certain valsartan products been shown to present</p> <p>16 a general or specific cancer risk."</p> <p>17 Are you offering that opinion or are -- is</p> <p>18 that -- or is that an assumption that you are</p> <p>19 stating?</p> <p>20 MR. STOY: Object to the form.</p> <p>21 You can answer.</p> <p>22 THE WITNESS: That's not a core opinion</p> <p>23 that I'm offering. That is something that I am</p> <p>24 citing -- it's my understanding that I'm citing from</p> <p>25 some literature that I reviewed but it's not central</p>	<p style="text-align: right;">Page 85</p> <p>1 question of whether the contaminated valsartan can</p> <p>2 cause cancer in this case?</p> <p>3 MR. STOY: Object to the form.</p> <p>4 THE WITNESS: In my report, there are some</p> <p>5 sources that I reviewed about what other agencies</p> <p>6 have said about the link between nitrosamines and</p> <p>7 the potential for cancer. But my core opinions do</p> <p>8 not concern that.</p> <p>9 BY MR. MIGLIACCIO:</p> <p>10 Q. Okay. Did you review any dietary studies</p> <p>11 that discussed increased risk of cancer at higher</p> <p>12 levels of NDMA ingestion?</p> <p>13 A. Yes.</p> <p>14 Q. You did?</p> <p>15 A. Strike that.</p> <p>16 I reviewed studies on the concentration of</p> <p>17 NDMA and NDEA in various dietary sources.</p> <p>18 I also reviewed sources that had</p> <p>19 estimates, for example, from the FDA on the</p> <p>20 potential risk of cancer given nitrosamines.</p> <p>21 Q. But you're not offering any opinions with</p> <p>22 respect to those studies?</p> <p>23 A. No.</p> <p>24 Q. Okay. When you say this isn't a core</p> <p>25 opinion that you're offering, does that mean this is</p>

<p style="text-align: right;">Page 86</p> <p>1 not an opinion that you would be testifying to at 2 trial if there was a trial in this case? 3 MR. STOY: Object to the form. 4 THE WITNESS: I wouldn't be testifying on 5 issues of general causation. 6 BY MR. MIGLIACCIO: 7 Q. Got it. 8 I want to direct you to paragraph 68 of 9 your complaint -- of your -- I'm sorry, your -- your 10 report where you discuss the M-E-P-S data. 11 A. The MEPS data. 12 Q. Right. 13 Can you tell me what MEPS data is? 14 A. Sure. I think that paragraph actually 15 does a pretty good job of doing that. 16 MEPS is a data source that's collected by 17 survey. It is a -- supposed to be a representative 18 survey of the U.S. population and it collects data 19 on healthcare utilization, healthcare -- health 20 insurance coverage. It also has information on 21 patient diseases and demographics. And it conducts 22 these surveys yearly. Doesn't necessarily follow 23 the same people all the time, but it conducts a 24 representative survey over time on -- on -- on this 25 type of information.</p>	<p style="text-align: right;">Page 88</p> <p>1 who took affected valsartan" -- and when we're 2 talking about affected valsartan we're talking about 3 the valsartan at issue in this case, right, that has 4 the nitrosamine contamination in it, right? 5 A. To be clear, affected valsartan is -- 6 we -- we would have to define it by an NDC code. 7 Q. Uh-huh. 8 A. We don't know anything more than that. We 9 don't know what the lot was that the patient took 10 the valsartan from. As would be the case for many 11 of the patients in the proposed class. But we know 12 the NDC number which means we know the manufacturer 13 of the valsartan. And that's what -- 14 Q. So that's what you're -- that's what 15 you're talking about when you're talking about 16 affected valsartan? 17 A. Right. So the valsartan may or may not 18 have actually contained nitrosamines but it was from 19 a manufacturer as specified by the NDC code. 20 Q. And you say 38 -- just to -- to continue 21 that sentence, "who took affected valsartan 22 (34.8 percent for diabetes, 20.2 percent for cancer) 23 was similar to the rate of individuals who took 24 non-affected valsartan (38.2 percent for diabetes 25 and 19.1 percent for cancer)."</p>
<p style="text-align: right;">Page 87</p> <p>1 Q. Who -- and who -- what organization 2 sponsors this or -- or, you know, collects the data? 3 A. I believe it's the federal government. 4 Q. Okay. And you directed that this data be 5 pulled for -- for patients who took affected 6 valsartan and non-affected valsartan? 7 A. As well as patients who don't take -- 8 Q. Valsartan at all. 9 A. We wanted to compare that. 10 I believe there are three -- three sets of 11 patients: patients who didn't take valsartan at 12 all, patients who took affected valsartan, patients 13 who took non-affected valsartan. 14 Q. Was -- how big is this sample, you know, 15 what -- what percentage would you say it -- it 16 captured of the population? 17 A. I can't -- I don't know exactly right now 18 but I know it's a representative sample and it's -- 19 the survey design is -- is meant to, you know, 20 survey enough people so that it -- you know, 21 inferences can be made with reasonable certainty on 22 a representative sample of the U.S. 23 Q. And I'm just looking at paragraph 68. 24 You state, "I found that the rate of 25 cancer and diabetes in the MEPS data for individuals</p>	<p style="text-align: right;">Page 89</p> <p>1 A. Correct. 2 Q. Could we agree that 20.2 percent is 3 greater than 19.1 percent? 4 A. It depends on the -- the -- the number -- 5 the number 20.2 and the number 19.1 in complete 6 isolation, if you were just to ask me which number 7 is greater, I would say 20.2. 8 But if you are doing a study on this you 9 would have to ask what the statistical significance 10 is between 20.2 and 19.1. You would also have to 11 ask whether this is clinically significant given -- 12 you know, this is not -- we're not using this as a 13 study of causation at all. 14 You know, you would have to -- you would 15 have to control for a number of different things in 16 order to kind of ask whether there's a clinically 17 and statistically meaningful relationship between 18 affected valsartan and cancer. This is simply 19 descriptive. 20 Q. You haven't done any of those things, 21 statistical study or clinical study on that, right? 22 A. On -- on causation? 23 Q. Yeah. With respect to this paragraph. 24 A. Correct. The goal of this is not to ask 25 whether valsartan could cause cancer -- affected</p>

<p style="text-align: right;">Page 90</p> <p>1 valsartan could cause cancer.</p> <p>2 Q. Got it.</p> <p>3 Do you have any experience -- we talked, I</p> <p>4 think at some length, about your -- you know, your</p> <p>5 work as a hospitalist, as -- as a physician.</p> <p>6 You know, do you have any experience</p> <p>7 setting up a medical monitoring program?</p> <p>8 A. No.</p> <p>9 MR. STOY: Object to the form.</p> <p>10 You can answer.</p> <p>11 THE WITNESS: Okay.</p> <p>12 No. By "medical monitoring" -- do you</p> <p>13 want to be a little bit more specific, actually,</p> <p>14 before I say --</p> <p>15 BY MR. MIGLIACCIO:</p> <p>16 Q. Yeah.</p> <p>17 Well, what experience do you have</p> <p>18 monitoring at-risk patient populations? I'll put it</p> <p>19 that way.</p> <p>20 A. Patients at risk for -- for what?</p> <p>21 Q. For cancer.</p> <p>22 A. As a hospitalist, I don't have -- it's not</p> <p>23 part of my job as a hospitalist to monitor at-risk</p> <p>24 patient populations for diseases that have not yet</p> <p>25 become known.</p>	<p style="text-align: right;">Page 92</p> <p>1 Q. They haven't specifically focused on that?</p> <p>2 A. They have not specifically focused on the</p> <p>3 process of making cancer diagnoses.</p> <p>4 Q. What -- what -- and it sounds like it's a</p> <p>5 pretty broad or general interest of yours. Can you</p> <p>6 explain a little bit more about, you know, are you</p> <p>7 writing it -- that as an economist? Like, what is</p> <p>8 the -- like, can you give me some more meat on the</p> <p>9 bone for that?</p> <p>10 MR. STOY: Object to the form.</p> <p>11 THE WITNESS: I'm writing about this as</p> <p>12 both a clinician and an economist. The -- I've</p> <p>13 written economics papers on the process of making</p> <p>14 diagnoses and how to understand kind of, you know,</p> <p>15 various tradeoffs between overdiagnosis versus</p> <p>16 underdiagnosis as well as the accuracy of the</p> <p>17 diagnosis process.</p> <p>18 Some -- some providers may make both more</p> <p>19 Type I errors and Type II errors, and it's not a</p> <p>20 tradeoff between those providers and other</p> <p>21 providers.</p> <p>22 So this economics literature is focused on</p> <p>23 systems of care, provider behavior, and kind of</p> <p>24 specific objects of diagnostic errors such as Type I</p> <p>25 errors and Type II errors.</p>
<p style="text-align: right;">Page 91</p> <p>1 Q. Got it.</p> <p>2 Have you -- have you done anything to</p> <p>3 monitor at-risk patient populations for diseases</p> <p>4 that have not become known? Have you done that in</p> <p>5 any other part of your work other than a</p> <p>6 hospitalist, like, you know, as -- in -- in academia</p> <p>7 or -- or elsewhere?</p> <p>8 MR. STOY: Object to the form.</p> <p>9 THE WITNESS: In academia, part of my</p> <p>10 research agenda is on the process of making</p> <p>11 diagnoses and part of that involves studying the</p> <p>12 properties of diagnostic tests and the -- the kind</p> <p>13 of human behavior that goes into the process of</p> <p>14 making diagnosis. So that would be related to this</p> <p>15 idea of screening for diagnoses, identifying</p> <p>16 diagnoses. That -- that's -- I think that's all I</p> <p>17 can say.</p> <p>18 I've studied it from an academic</p> <p>19 perspective that's interested in the process of</p> <p>20 making diagnoses.</p> <p>21 BY MR. MIGLIACCIO:</p> <p>22 Q. The process of making diagnoses, have they</p> <p>23 related to cancers?</p> <p>24 A. They could certainly be applied to the</p> <p>25 process of diagnosing cancers.</p>	<p style="text-align: right;">Page 93</p> <p>1 I have applied this type of research for a</p> <p>2 clinical audience as well. I'm working on an</p> <p>3 opinion piece in JAMA for a clinical audience that</p> <p>4 talks about diagnostic efficiency, what makes for</p> <p>5 diagnostic errors, and how can we improve the</p> <p>6 quality of diagnoses.</p> <p>7 BY MR. MIGLIACCIO:</p> <p>8 Q. These -- this research, is it fair to say,</p> <p>9 has not focused on specific patient subpopulations</p> <p>10 who are at risk for cancer?</p> <p>11 A. It has not specifically focused on that,</p> <p>12 so -- population. It has kind of viewed the process</p> <p>13 of diagnoses more broadly.</p> <p>14 But, you know, the diagnosis of cancer is</p> <p>15 one of the major -- one of the -- one of the most</p> <p>16 important kind of domains of diagnostic</p> <p>17 decision-making. I would say cancer is -- is quite</p> <p>18 important in terms of diagnostic error,</p> <p>19 misdiagnoses, and how we can improve our process of</p> <p>20 making diagnoses.</p> <p>21 Q. Do you have -- I think -- now -- I think I</p> <p>22 asked this one way. I'll ask it another way.</p> <p>23 Do you have any experience administering a</p> <p>24 medical monitoring program --</p> <p>25 A. No.</p>

<p>Page 94</p> <p>1 Q. -- to monitor a group?</p> <p>2 Before you offered your opinion here in</p> <p>3 this case, have you had any litigation experience</p> <p>4 with opining relating to -- offering an opinion with</p> <p>5 respect to medical monitoring?</p> <p>6 A. With respect to medical monitoring for</p> <p>7 patients at risk for cancer?</p> <p>8 Q. Yes.</p> <p>9 A. No.</p> <p>10 Q. Okay. Any other aside from that narrow</p> <p>11 group, anything broader?</p> <p>12 A. Some of my other opinions relate to</p> <p>13 physician behavior. And physician behavior -- an</p> <p>14 important part of physician behavior is deciding</p> <p>15 whether a certain treatment is appropriate for a</p> <p>16 patient or deciding whether a certain test is</p> <p>17 appropriate for a certain patient. And that relates</p> <p>18 to diagnoses, making diagnoses.</p> <p>19 Q. Okay. Do you know of any medical</p> <p>20 monitoring programs that have been, you know,</p> <p>21 approved by courts?</p> <p>22 MR. STOY: Object to the form.</p> <p>23 THE WITNESS: I haven't researched which</p> <p>24 medical monitoring programs have been approved by</p> <p>25 courts.</p> <p>Page 95</p> <p>1 BY MR. MIGLIACCIO:</p> <p>2 Q. Got it.</p> <p>3 Have you looked or researched into -- of</p> <p>4 any medical monitoring programs in the United States</p> <p>5 that are not approved by courts? And I'm talking</p> <p>6 about programs outside of the guidelines that you</p> <p>7 reference in your report.</p> <p>8 MR. STOY: Object to form.</p> <p>9 THE WITNESS: Can you state that again,</p> <p>10 please?</p> <p>11 BY MR. MIGLIACCIO:</p> <p>12 Q. Yeah.</p> <p>13 Have you looked at or researched any</p> <p>14 medical monitoring programs in the United States</p> <p>15 that -- that aren't court-approved, you know, like</p> <p>16 there's the 9/11 medical monitoring program, is that</p> <p>17 something you've looked at, ever?</p> <p>18 MR. STOY: Object as to form.</p> <p>19 THE WITNESS: I can't recall whether I've</p> <p>20 looked at that or not, whether I've looked at the</p> <p>21 9/11 program.</p> <p>22 BY MR. MIGLIACCIO:</p> <p>23 Q. For -- that -- that was just an example.</p> <p>24 I mean, you know, there may be others.</p> <p>25 But you can't recall any others?</p>	<p>Page 96</p> <p>1 A. No.</p> <p>2 Q. Okay. I want to direct you to</p> <p>3 paragraph 32 in your report.</p> <p>4 A. Okay.</p> <p>5 Q. Okay. And I'm -- I'm going down toward</p> <p>6 the -- I guess it's the one -- second -- the third</p> <p>7 sentence where -- that begins, "In contrast."</p> <p>8 And it says, "In contrast the screening</p> <p>9 guidelines I discuss in this section refer to the</p> <p>10 testing of an apparently healthy, asymptomatic</p> <p>11 target population."</p> <p>12 A. Right.</p> <p>13 Q. Would you agree that the screening</p> <p>14 guidelines that you have discussed in this report</p> <p>15 are for the average risk population?</p> <p>16 A. I am not sure about that. The</p> <p>17 guidelines -- some of these guidelines are for</p> <p>18 smokers, for example. I don't know what you mean by</p> <p>19 "average risk population."</p> <p>20 I -- here, I say patients without</p> <p>21 symptoms.</p> <p>22 Q. Aside from smokers -- smokers have a</p> <p>23 special set of guidelines, right?</p> <p>24 A. Right.</p> <p>25 Q. I think you discussed them. And maybe you</p> <p>Page 97</p> <p>1 might have discussed one other. But smokers have --</p> <p>2 they get low-dose CT scans.</p> <p>3 What is the guideline for smokers again?</p> <p>4 A. I believe that's in my report in</p> <p>5 Figure number 1.</p> <p>6 Q. Figure 1. Okay.</p> <p>7 A. Yeah. Would you like to turn to that?</p> <p>8 Q. Sure.</p> <p>9 A. Okay. So for lung cancer, the USPSTF has</p> <p>10 a recommendation of "B" for adults aged 50 to 80</p> <p>11 with a 20 pack-year smoking history who currently</p> <p>12 smoke or quits within the last 15 years.</p> <p>13 Q. And you reference the USPSTF; is that</p> <p>14 right?</p> <p>15 A. Yes. Uh-huh.</p> <p>16 Q. Who -- what organization is the USPSTF?</p> <p>17 A. The USPSTF is the U.S. Preventive Services</p> <p>18 Task Force, and that is the main organization that</p> <p>19 comes up with guidelines related to preventive</p> <p>20 services.</p> <p>21 My boss is a member of this task force.</p> <p>22 It's a -- it's -- it's a high profile task force</p> <p>23 that considers evidence on various -- various</p> <p>24 population-based guidelines -- I'm sorry, various</p> <p>25 population-based interventions that you could do</p>
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<p style="text-align: right;">Page 98</p> <p>1 or -- or -- or screening tests. And it issues 2 recommendations based on this evidence. 3 Q. Have you ever been a member of the USPS -- 4 USPSTF? 5 A. No. 6 Q. Okay. The NCI, you referenced the 7 National Cancer Institute. What -- what does the 8 NCI do? 9 A. The National Cancer Institute is an 10 organization that is an authority on cancer, 11 various -- and in this -- and in this setting, the 12 NCI -- I refer to the NCI if it has any guidelines 13 with respect to screening of cancer. 14 Q. Are you familiar with the National 15 Comprehensive Cancer Network, or NCCN? 16 A. I've heard of that organization. 17 Q. Do -- what do you know about the NCCN? 18 A. I know that that organization also puts 19 out quality measures on cancer care. I'm not sure I 20 know very much more about the NCCN. 21 Q. Is it fair to say that the development and 22 treatment -- the development and establishment of 23 treatment guidelines for cancer has not been a focus 24 area of your research; is that fair to say? 25 MR. STOY: Object to the form.</p>	<p style="text-align: right;">Page 100</p> <p>1 A. Yeah. Let's turn to the CV. 2 Q. Okay. 3 A. This is in -- under working paper number 2 4 on page A-2. 5 Q. A-2? 6 A. Yeah. 7 Q. Okay. 8 "Fixing Misallocation with Guidelines"? 9 A. Correct. 10 Q. "Awareness versus Adherence"? 11 A. Correct. 12 Q. Got it. 13 NBER, National Bureau of Economic 14 Research? 15 A. Exactly. 16 Q. And you have an appointment or -- with 17 that group right now? 18 A. I do. I have an affiliation with that 19 group. 20 Q. Okay. You've had that for a long time? 21 A. I've had -- well, it's something that you 22 need to be nominated and I guess approved for by 23 the -- this is something that I got in my first year 24 as a faculty. It's called -- it's in my CV under 25 "Faculty Research Fellow, National Bureau of</p>
<p style="text-align: right;">Page 99</p> <p>1 THE WITNESS: Could you say that again? 2 BY MR. MIGLIACCIO: 3 Q. That is it fair to say that the 4 development and establishment of treatment 5 guidelines for cancer has not been a focus of your 6 research? 7 A. The -- 8 MR. STOY: Object to the form. 9 THE WITNESS: The development and -- of 10 cancer -- the development of cancer guidelines has 11 not been a focus of my research. I have focused on 12 other types of guidelines in my research. 13 BY MR. MIGLIACCIO: 14 Q. What other types of guidelines have you 15 focused on? 16 A. Specifically, I focused on guidelines for 17 the treatment of atrial fibrillation, which in -- 18 you know, which are similar in ways that you are 19 developing guidelines based on evidence. There are 20 risks and benefits for recommending a certain course 21 of action for a broad set of patients. And in this 22 particular research, I'm interested in how providers 23 respond to guidelines. 24 Q. So could you -- could you direct me to any 25 papers you have on that subject?</p>	<p style="text-align: right;">Page 101</p> <p>1 Economic Research." 2 Q. Got it. Got it. Got it. Okay. 3 And this working paper was published in 4 July of last year? 5 A. That was the most recent version of the 6 paper, correct. 7 Q. Oh. Has -- it's changed over time? Have 8 there been -- 9 A. Yeah, you can see previous versions of the 10 paper if you go to that website. 11 Q. Got it. Got it. 12 And have they all -- have they all related 13 to atrial fibrillation or have they -- those papers 14 changed their focus? 15 A. The -- the empirical focus of the paper 16 has been on atrial fibrillation throughout. The 17 paper of course is motivated much more broadly. 18 It's motivated about how do we form guidelines, how 19 do physicians respond to guidelines; if you're 20 trying to optimize outcomes for a patient 21 population, how should you best make use of 22 guidelines. 23 Q. Your coauthors, there are -- it looks like 24 one, two, three -- four other authors? 25 A. Right.</p>

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1 Q. Have they been the same authors on -- on
 2 this series of papers over time or has it -- has it
 3 changed?
 4 A. I believe it's been the same for -- ever
 5 since we've had a working paper, it's been the same.
 6 Q. Are they physicians or economists or both?
 7 A. Both.
 8 Q. All right. So all four are
 9 physician/economists?
 10 A. Oh, sorry. Two of them are -- three --
 11 two of them economists. Leila Agha and Jason
 12 Abaluck are economists. Daniel Singer is a
 13 physician. And Diana Zhu is a Ph.D. student in
 14 economics.
 15 Q. Got it.
 16 Have you contributed in any way to the
 17 development of a USP -- P -- USPSTF guideline
 18 relating to cancer?
 19 A. No.
 20 Q. Have you contributed to the evidence-based
 21 reviews provided by the NCI as referenced in your
 22 report, I think paragraph 35?
 23 A. Paragraph 35.
 24 Q. I mean, I'm not saying that you did. I'm
 25 just asking. That -- that's my -- I think you --

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1 you discuss the evidence-based review that NCN
 2 does -- NCI does?
 3 A. Uh-huh.
 4 No, I have not.
 5 Q. Okay. Do you consider yourself to be an
 6 expert in the formulation of the derivation of the
 7 original clinical guidelines in the screening for
 8 cancers?
 9 A. The formulation or derivation?
 10 Q. Uh-huh.
 11 A. Could you clarify that?
 12 Q. Or the creation --
 13 A. Okay. Do I --
 14 Q. -- of the clinical guidelines?
 15 A. Okay. Sorry, could you restate the
 16 question?
 17 Q. Yeah.
 18 A. Do I consider myself an expert in?
 19 Q. In the creation of clinical guidelines for
 20 the screening of cancers?
 21 A. No.
 22 MR. STOY: Object to the form.
 23 Go ahead.
 24 BY MR. MIGLIACCIO:
 25 Q. Can we agree that it can take a long time

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1 to get screening procedures added to national
 2 guidelines at USPSTF?
 3 MR. STOY: Object to the form.
 4 THE WITNESS: I don't know what I would
 5 characterize as a long time. I think it's --
 6 there's a reason why we don't -- we require a
 7 certain level of evidence in order to change a
 8 guideline. Because evidence is incremental and
 9 because evidence can change we want to have a
 10 certain level of certainty whenever we have a type
 11 of guideline.
 12 And as I discuss in my report, when the
 13 guidelines are for screening, we have to be very
 14 cognizant of the potential risks of screening. And
 15 that's why I think we would have just a higher bar
 16 to -- to, you know, recommending a guideline for
 17 a -- a new guideline for screening.
 18 BY MR. MIGLIACCIO:
 19 Q. And for -- for example, you know, can we
 20 agree that it took many years before low-dose CT
 21 scans were added as a guideline for tobacco users?
 22 MR. STOY: Object to form.
 23 THE WITNESS: I don't know the particular
 24 history of that. Are you specifically referring to
 25 low-dose CT scans as opposed to chest x-rays?

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1 BY MR. MIGLIACCIO:
 2 Q. Uh-huh.
 3 A. I would need to look into the history of
 4 when low-dose CT scans were available. And, you
 5 know, there is a certain -- as I discuss in my
 6 report, one of the considerations of using a certain
 7 technology for screening is characterizing the
 8 performance of that technology in terms of false
 9 positives and false negatives as well as
 10 characterizing any risk that may come from using
 11 this new technology of a CT scan versus a chest
 12 x-ray. I would imagine even if it's low dose, there
 13 would be much more radiation than the chest x-ray.
 14 Q. Can you -- there'd be more radiation from
 15 a low-dose CT scan than a chest x-ray?
 16 A. Than a chest x-ray. I would imagine that
 17 a CT scan -- a usual CT scan has I think orders of
 18 magnitude, more radiation than a single plain film
 19 chest x-ray, and even if it's a low-dose CT scan I
 20 would have to -- I would have to look at -- review
 21 the evidence, but I think there would still be some
 22 concern of higher radiation from a low-dose CT scan
 23 than a chest x-ray.
 24 Q. But you're not offering that opinion here
 25 and now? You don't know the answer to that without

<p style="text-align: right;">Page 106</p> <p>1 reviewing the information?</p> <p>2 A. Correct. I don't know in that specific</p> <p>3 case. But I would -- and what -- but what is</p> <p>4 central to my opinions is that all of these</p> <p>5 screening tests have potential risks both in terms</p> <p>6 of false positives and false negatives so that's why</p> <p>7 you need to understand the testing characteristics</p> <p>8 for a certain screening procedure but also some of</p> <p>9 these screening procedures have physical risks such</p> <p>10 as radiation.</p> <p>11 Q. I will be going through more of your</p> <p>12 report. I think you -- so to -- I think you have --</p> <p>13 you have stated in your report that certain</p> <p>14 thresholds need to be met.</p> <p>15 And I think that's what you're saying now</p> <p>16 before a screening guideline is made; fair to say?</p> <p>17 A. Correct.</p> <p>18 Q. And I'll direct you to some portions of</p> <p>19 your report on that in -- in a moment.</p> <p>20 MR. STOY: Nick, before we --</p> <p>21 MR. MIGLIACCIO: Yeah.</p> <p>22 MR. STOY: If you're about to jump to</p> <p>23 another topic, we've been going a little over an</p> <p>24 hour now.</p> <p>25 MR. MIGLIACCIO: Yes.</p>	<p style="text-align: right;">Page 108</p> <p>1 of asymptomatic patients."</p> <p>2 And then you say below, "In my opinion,</p> <p>3 the evidence related to NDMA and NDEA in affected</p> <p>4 valsartan fails to meet the bar required to use a</p> <p>5 uniform screening process on a broad population of</p> <p>6 asymptomatic patients."</p> <p>7 Do you have a -- what do you mean by "a</p> <p>8 high threshold must be met for a risk factor to be</p> <p>9 incorporated into a guideline to screen</p> <p>10 populations"?</p> <p>11 A. I believe there's another part of my</p> <p>12 report that kind of elaborates on this threshold.</p> <p>13 Q. Okay.</p> <p>14 A. Right. So I think paragraph 35 gets at</p> <p>15 this here. Here I talk about the USPSTF guidelines.</p> <p>16 But I think it's -- it's broadly applicable to the</p> <p>17 general framework we would need to consider a</p> <p>18 threshold.</p> <p>19 Would you like me to read the relevant</p> <p>20 sentence?</p> <p>21 Q. Sure.</p> <p>22 A. "USPSTF recommendations are based on a</p> <p>23 framework which considers questions such as whether</p> <p>24 screening may reduce morbidity; whether sufficiently</p> <p>25 sensitive and specific screening tests are</p>
<p style="text-align: right;">Page 107</p> <p>1 MR. STOY: Would this be a good time for a</p> <p>2 quick break?</p> <p>3 MR. MIGLIACCIO: Yeah, I think so. Why</p> <p>4 don't we go on off the record and we can discuss how</p> <p>5 long.</p> <p>6 MR. STOY: Okay.</p> <p>7 THE VIDEOGRAPHER: Off the record at</p> <p>8 10:19 a.m. Pacific time.</p> <p>9 (Whereupon, a brief recess was taken.)</p> <p>10 THE VIDEOGRAPHER: We are back on the</p> <p>11 record. The time is 10:44 a.m. Pacific time.</p> <p>12 BY MR. MIGLIACCIO:</p> <p>13 Q. Okay. Great. All right.</p> <p>14 Dr. Chan, I think we were talking before</p> <p>15 the break about thresholds and I want to ask you</p> <p>16 some questions about that.</p> <p>17 I direct you to paragraph 16 of your</p> <p>18 report.</p> <p>19 A. Okay.</p> <p>20 Q. Okay. And I want to direct you to midway</p> <p>21 through it, there's a sentence that says, "While</p> <p>22 there are many risk factors for the nine types of</p> <p>23 cancers identified by Plaintiffs in this case, a</p> <p>24 high threshold must be met for a risk factor to be</p> <p>25 incorporated into a guideline to screen populations</p>	<p style="text-align: right;">Page 109</p> <p>1 available; whether early detection and treatment</p> <p>2 makes a difference in morbidity; and what the</p> <p>3 potential harms of screening and subsequent</p> <p>4 screening-implied treatment may be."</p> <p>5 So this sentence does not specifically</p> <p>6 mention the agent in question, such as NDMA and</p> <p>7 NDEA, but the agent in question and the potential</p> <p>8 cancer type related to this agent bears on many of</p> <p>9 these factors in this sentence such as whether a</p> <p>10 screening may reduce morbidity.</p> <p>11 The agent needs to be sufficiently</p> <p>12 associated with cancer in the sense that we expect</p> <p>13 sufficiently high number of patients associated with</p> <p>14 this agent or this risk factor, for screening to</p> <p>15 reduce morbidity.</p> <p>16 Q. And you're -- but you are not offering, as</p> <p>17 we discussed, a general causation opinion here,</p> <p>18 you're not offering an opinion on -- on what you've</p> <p>19 just said?</p> <p>20 A. I'm not --</p> <p>21 MR. STOY: Object to the form.</p> <p>22 Sorry, Doctor.</p> <p>23 THE WITNESS: It's not my assignment to</p> <p>24 offer an opinion on causation, but as I mentioned</p> <p>25 earlier, I refer to sources that have some estimate</p>

<p style="text-align: right;">Page 110</p> <p>1 of the associated -- a potential associated cancer 2 risk. 3 So, for example, in paragraph 88 of the 4 report, I cite a very conservative estimate, meaning 5 like a worst -- somewhat of a worst-case scenario 6 that the FDA has estimated that the highest dose of 7 valsartan, one additional cancer case may be 8 expected per 8,000 patients exposed to NDMA 9 containing valsartan. And one additional cancer 10 case maybe expected per 18,000 patients exposed to 11 NDEA containing valsartan. 12 Q. Yes. And I -- yeah, I do -- I do see 13 that. 14 "The maximum exposure to NDMA from 15 affected valsartan is approximate" -- "of 29,498 16 micrograms is approximately 12 times the lifetime 17 acceptable intake, implying an excess cancer risk of 18 12 in 100,000 or approximately 1 in 8,000," right, 19 of paragraph 92? 20 A. Yes. I was reading paragraph 88 but part 21 of 92 also mentions. 22 Q. I'm sorry, I think I said paragraph 93, 23 but I may have that wrong, I may have said -- 24 given -- yeah, I was referring to paragraph 93. 25 A. Okay. Yep, I see that you're reading</p>	<p style="text-align: right;">Page 112</p> <p>1 my saying that the R or the threshold is quite high. 2 If you look at the risk factors that make 3 it into a screening guideline, as I read, there are 4 a number of different criteria that need to be met 5 and one of those criteria include a high risk of 6 cancer. 7 BY MR. MIGLIACCIO: 8 Q. And is your opinion, is that 1 in 8,000 is 9 not a high risk of cancer? 10 A. I think compared to some of the other 11 risks that I mention in my report it's much lower. 12 Q. Where do you draw the line as a high risk 13 or low risk, what is the -- what is the numerical 14 threshold? Do you have one? 15 A. I'm not sure if I can say precisely where 16 it is, but I can say that 1 in 8,000 is an order or 17 two of magnitude lower than some of the other risks 18 that we have and many of these other risks don't 19 make it into broad population guidelines. 20 Q. What other risks that we have are you 21 referring to? 22 A. Yeah, it's in my report. If I can refer 23 to that. 24 For example, radiation, I think is one 25 thing that I do mention in my report.</p>
<p style="text-align: right;">Page 111</p> <p>1 paragraph 93. 2 Q. Yeah. 3 A. And I was reading from 88. 4 Q. Is this 1 in 8,000 risk an acceptable 5 cancer risk to you as a physician? 6 MR. STOY: Object to the form. 7 THE WITNESS: I'm not sure what you mean. 8 MR. STOY: I'm sorry. I just want to add 9 an objection to the extent it's outside the scope 10 of -- of Dr. Chan's report. 11 Go ahead. I'm sorry. 12 THE WITNESS: Right. I'm not sure what 13 you mean by "acceptable cancer risk," and I'm 14 commenting on this not as a physician per se, but in 15 my analysis of what organizations like the USPSTF 16 and NCI have -- what types of risk factors have made 17 it into a guideline. 18 So if you look at Figure 1 and Figure 2 of 19 my report, particularly Figure 2, there are a number 20 of different risk factors that are associated with 21 all of these nine cancers. And in my report, I talk 22 about the magnitude of some of these risk factors. 23 Some of these risk factors are quite -- 24 much higher than the 1 in 8,000 for NDMA and 1 in -- 25 did I say 18,000 for NDEA. And that is the basis of</p>	<p style="text-align: right;">Page 113</p> <p>1 Yes, so I believe this is in figure -- 2 this is in Figure 2 and paragraph 42 of my report. 3 The risk for lung cancer including one 4 first degree family member affects -- so family 5 history, you know, you have, like, a relative risk 6 of 2.59 -- 57. You have radiation therapy at 7 relative risk of two. 8 And if you convert these to number of 9 people you would need to screen to get one cancer, 10 they would be much higher than the number that I 11 just cited for NDMA and NDEA. 12 The relative risk for lung cancer of 8 13 of -- of a 20- to 30-pack history of smoking is 8 -- 14 8.2. So that's substantially even higher than the 15 other relative risk that I just cited. 16 And if you convert these to number of 17 people you would need to screen to find one patient 18 with a -- who truly has the cancer they would be 19 much, much -- much lower than you would need for 20 NDMA and NDEA. 21 Q. What is the type of -- of screening that's 22 done for lung cancer? 23 A. I believe that's in my report. That 24 should be in Figure 3. 25 So in Figure 3, there are a number of</p>

<p style="text-align: right;">Page 114</p> <p>1 different potential options and the one that is 2 recommended is low-dose CT scan currently. 3 Q. And as you testified earlier, that may 4 have a higher radiation dosage than a regular x-ray? 5 A. Higher, correct. 6 Q. Higher. Got it. 7 So that there is, in your opinion, a 8 certain degree of risk that is associated with a 9 low-dose CT scan? 10 A. Right. 11 Q. Got it. 12 I see in paragraph 42, you cite to 13 epidemiology studies in footnotes 59 and 60. 14 A. Uh-huh. 15 Q. But you have not done so with respect to 16 NDMA, you have not looked at the -- right, at least 17 I don't see the citations for the -- for 18 epidemiology studies and relative risk associated 19 with NDMA. Or if I am missing something you can 20 point it to me. 21 MR. STOY: Object to the form. Object to 22 the extent it mischaracterizes the report. 23 Go ahead. 24 THE WITNESS: The report does cite the FDA 25 calculation for the number of additional cases of</p>	<p style="text-align: right;">Page 116</p> <p>1 the most conservative in the sense that they are 2 considering the highest dose of NDMA and NDEA and 3 over a long period of time. 4 Q. And you haven't looked at this, though, to 5 offer that opinion, you're -- this is like ancillary 6 to -- to your opinion? 7 A. This is -- 8 MR. STOY: Object -- hang on, Doctor. 9 Object to the form of the question to the 10 extent it mischaracterizes. 11 Go ahead. 12 THE WITNESS: I would characterize this as 13 this is an input into my opinion in the sense that 14 I've looked at a range of sources that have various 15 linkages between NDMA and affected valsartan to 16 cancer. Some of which are no linkage. 17 And if I take the most conservative 18 estimate, meaning the highest risk, and compare that 19 to some of the other risks that I list in 20 paragraph 42 and Figure 2, that linkage between NDMA 21 and NDEA and kind of more importantly the linkage 22 between affected valsartan and cancer is low. 23 BY MR. MIGLIACCIO: 24 Q. And, you know, to be clear, you have not 25 looked at any of the other plaintiffs' expert</p>
<p style="text-align: right;">Page 115</p> <p>1 cancer potentially in -- you know, with the highest 2 dose of NDMA and NDEA. And that I think can be 3 converted to a relative risk. I'm not sure if in 4 the report we've done that, but it could be -- it 5 could certainly be converted to a relative risk. 6 BY MR. MIGLIACCIO: 7 Q. Fair to say, though, the sole basis for 8 your opinion, then, on the -- I'll -- what I'll say 9 is your view that there's a low relative risk, and 10 you can tell me if I'm wrong about that, is the FDA 11 citation that you give here; is that fair? 12 A. I don't think it's the sole basis. There 13 are other sources that I do cite that are even -- 14 that have a lower to potential -- other sources 15 don't demonstrate a risk of cancer in humans to -- 16 you know, based on on NDMA or NDEA, and I believe 17 I've cited one of those sources. 18 So I think there's a range of potential 19 linkages between NDMA and NDEA to cancer, in 20 particular, valsartan -- affected valsartan to 21 cancer. As I said earlier, causation is not, you 22 know, my -- my main area of focus here. 23 But the magnitude of any potential linkage 24 is relevant to my opinions and that's where I 25 believe the FDA estimate of the linkage is perhaps</p>	<p style="text-align: right;">Page 117</p> <p>1 reports other than the ones we have discussed 2 already today? 3 A. Correct. 4 Q. So the threshold that you're identifying, 5 I see that you cite to paragraph 40 in -- you cite 6 in paragraph 35 to a study or an article in 7 footnote 47. 8 Do you see that? By Vearrier and 9 Greenberg? 10 A. Correct. 11 Q. That -- that's the sole citation you have 12 for that -- that sentence that you read to me 13 earlier about what USPSTF recommendations are based 14 on, right? 15 A. That is the only citation in that 16 footnote, but I don't think it's -- it's not really 17 the only source that I have for that statement. In 18 fact, that might be a -- you know, this -- this 19 citation is about the implementation of medical 20 monitoring programs following potentially hazardous 21 exposures, a medical-legal perspective, this seems 22 like it's a comment -- it's a perspective in a 23 framework on how we should think about medical 24 monitoring programs. 25 But there -- if you read all of the USPSTF</p>

<p style="text-align: right;">Page 118</p> <p>1 recommendations, which are in separate cites, I 2 don't kind of list them as cites for that particular 3 sentence, but they could very well be related. If 4 you read any of those USPSTF recommendations, they 5 do walk you through a way of thinking about this 6 framework. 7 Q. So fair to say there is -- you don't 8 have -- or you're not offering a numerical 9 threshold -- or you're not offering an opinion that 10 there is a numerical threshold, but you just, you 11 know, add as to whether a monitoring program would 12 be appropriate? 13 A. I think based on the sentence that I read 14 in paragraph 35, this is a multidimensional 15 consideration. It can -- it depends on a number of 16 different considerations and therefore, if it 17 depends on all of these things, it shouldn't -- one 18 threshold, it wouldn't be a single scale or 19 threshold based on the risk of cancer. 20 That's one important consideration, but 21 there are other considerations that I just read from 22 that sentence. 23 Q. Uh-huh. So when you talk about threshold, 24 you say "a high threshold," you know, I think you 25 used that terminology maybe once, twice, three times</p>	<p style="text-align: right;">Page 120</p> <p>1 Does that mean a group of people who are 2 not at increased risk, excluding of course the 3 smokers that we've talked about? 4 A. No. I think by definition, any population 5 that you're going to specify screening for has to be 6 at increased risk. What I mean by asymptomatic 7 means that they don't have symptoms. 8 So if you are talking about lung cancer, 9 they don't have a cough that you want to kind of 10 evaluate further. If you're talking about colon 11 cancer they don't have abdominal pain. They don't 12 have symptoms, but they could be at increased risk. 13 Q. What are the increased risks that are -- 14 that are found in the broad asymptomatic population? 15 A. I believe that's in Figure 2. 16 Q. Okay. 17 A. Figure 2, I list the number of different 18 risk factors for each type of cancer in the last 19 column, Figure 2. 20 Q. Colorectal. And we've discussed this 21 already, colorectal and lung, there are these 22 additional screening guidelines for people at 23 increased risk, right? 24 A. There are guidelines to screen certain 25 populations based on age in the setting of</p>
<p style="text-align: right;">Page 119</p> <p>1 in the report. That's -- what you're referring to 2 is this paragraph? 3 A. What I -- yeah, when I say "threshold" I 4 don't mean a single number that is -- maps to the 5 risk of cancer. What I mean is a decision-making 6 threshold that considers a number of different 7 factors and a lot of these factors are 8 individualized for a clinician to reach a 9 decision-making threshold for a given patient. 10 And there's a separate threshold that you 11 might make for a guideline to screen a population of 12 asymptomatic patients and this would also similarly 13 consider a number of different factors here that I 14 just read. 15 Q. And that's -- that second threshold is the 16 one that I -- I was talking about. 17 A. Right. 18 Q. And that's what I think you're referring 19 to in your report for -- for the guidelines? 20 A. Correct. 21 Q. Going back to paragraph, I think 32, and I 22 think I asked you about the -- the types of -- the 23 screening guidelines that you have cited elsewhere 24 in your report and -- and you've referred to a broad 25 population of asymptomatic patients.</p>	<p style="text-align: right;">Page 121</p> <p>1 colorectal cancer, and based on age and smoking 2 history in the setting of lung cancer. 3 Q. Got it. 4 Those are used to define populations for 5 an asymptomatic testing but -- and in -- correct? 6 A. I'm sorry? 7 Q. I said those are used to define the 8 populations for asymptomatic testing? 9 A. Those are used to -- correct. Correct. 10 Q. Would you agree that blood tests and stool 11 tests proposed by Dr. Kaplan are not highly 12 invasive? 13 MR. STOY: Object to the form. 14 Go ahead. 15 THE WITNESS: Do you want to define 16 "invasive"? 17 BY MR. MIGLIACCIO: 18 Q. Yeah, I mean, I think you talk about the 19 risks that certain test -- tests may -- may have for 20 people. And I think you said physical risks 21 earlier? 22 A. Right. 23 Q. I think you talk about risks. Do blood 24 tests or stool tests present physical risks to 25 patients?</p>

<p style="text-align: right;">Page 122</p> <p>1 A. They don't -- you're right that they don't 2 present physical risks. The physical risks would be 3 quite minor. But they are not great tests. And if 4 you look at Figure 3, you'll see that there's really 5 not a recommendation to use many blood tests in most 6 cases. 7 And even for stool tests, you know, a lot 8 of people have colonoscopies rather than fecal -- 9 what are called blood -- you know, basically stool 10 tests for colon cancer. 11 So what I also talk about in my report is 12 not just the risk of a physical harm from the 13 screening procedure, it is the risk of getting a 14 false positive and false negative. 15 And if you use tests with lower 16 sensitivity or specificity to screen in a population 17 that is not at particularly high risk for the 18 cancer, you're at risk for getting false positives 19 and false negatives, and that can harm the patient. 20 There are ways in which that can set the patient 21 down a path that would be harmful. 22 Q. You talk about scrutiny-dependant cancers. 23 I think in paragraph 53. 24 A. Uh-huh. 25 Q. And I think you reference four cancers:</p>	<p style="text-align: right;">Page 124</p> <p>1 to treat the cancer has not necessarily gotten 2 better. And the underlying nature of the cancer 3 when it is, you know, newly detectable may not imply 4 anything toward quality of life or for life 5 expectancy. 6 So the definition of scrutiny-dependent 7 could change over time depending on the technology 8 to screen and the technology to treat. 9 Q. Got it. 10 Do you have any evidence, though, or any 11 opinion right now that any of those seven cancers I 12 just detailed are scrutiny-dependent? 13 A. I haven't thought hard enough -- haven't 14 thought about it long enough at this point. I could 15 return to that at some later point but at this 16 moment of the deposition, I can't offer an opinion 17 on that. 18 Q. Got it. 19 Is there any way for a physician to know 20 that a certain cancer when caught very early, let's 21 say prostate cancer, I'm just giving an example -- 22 A. Uh-huh. 23 Q. -- you know if it's caught very early, if 24 it is going to be aggressive or if it is not going 25 to be aggressive?</p>
<p style="text-align: right;">Page 123</p> <p>1 prostate, breast, thyroid, and lung. 2 Do you see that? 3 A. Yes. 4 Q. Do you understand that there are nine 5 cancers that Dr. Kaplan has offered an opinion about 6 in this case? 7 A. Yes. 8 Q. Okay. Are you offering the opinion that 9 the following cancers are what you'd call 10 scrutiny-dependent: liver, stomach, colorectal, 11 intestinal, esophageal, bladder, pancreatic, and 12 blood? 13 A. These -- what I cite as scrutiny-dependent 14 cancers in this paragraph are examples. I haven't 15 ruled out the possibility that other cancers could 16 also be scrutiny-dependent. 17 Whether a cancer is scrutiny-dependant or 18 not depends on the technology that we have. It may 19 not be scrutiny-dependant now but it could be 20 scrutiny-dependent later. It depends on the -- of 21 course the nature of the cancer, but also the nature 22 of treatment that we have available for that cancer. 23 So what makes it scrutiny-dependent is 24 that our technology to detect the cancer, if we look 25 hard enough, has gotten better. But our technology</p>	<p style="text-align: right;">Page 125</p> <p>1 A. I think there are ways to have an educated 2 guess. Not being an oncologist myself so I don't 3 consider myself an expert on prostate cancer, but 4 I'm -- know more about prostate cancer than the 5 average person. 6 There are ways where you could consider 7 epidemiology, what happens to the average patient 8 that you diagnose with prostate cancer with a given 9 PSA test, for example. And is there variation when 10 you have a given PSA test. That kind of -- and 11 reflects on the quality of the PSA test, which we 12 know to be not great. When you have patients who 13 can have the same PSA test but have -- you know, a 14 test could be neither sensitive nor specific if like 15 the test -- knowing the test doesn't give you that 16 much information. 17 So, again, you can know the general 18 epidemiology of what happens for a patient with 19 these given characteristics and their diagnosis with 20 prostate cancer. You could also ask what happens 21 when you have additional clinical information such 22 as the PSA test and what that means for the 23 possibilities of whether that cancer is going to be 24 aggressive or not. 25 Q. But I think you said it would be an</p>

<p style="text-align: right;">Page 126</p> <p>1 educated guess, really, there's not a way to know 2 whether? 3 A. We -- we -- 4 Q. -- it's aggressive or not? 5 A. It's -- it's kind of a spectrum. We 6 wouldn't know in general with certainty. But we 7 would have an educated guess and sometimes we would 8 know more and sometimes we would know less. 9 Q. Uh-huh. So from the time, let's say, a 10 prostate cancer is -- it's diagnosed, right, by a -- 11 by a biopsy, right? Am I wrong about that? 12 A. You know more -- you know the most about 13 it, yes, after you've actually taken tissue out and 14 you've kind of looked at that tissue with -- with 15 pathology. 16 Q. Right. That's -- is that when the 17 prostate cancer diagnosis is made or is it made 18 based on PSA levels? 19 A. It would require tissue to diagnose 20 prostate cancer. 21 Q. So if you do -- if you take a tissue 22 pathology of prostate cancer, can you know with the 23 result of that pathology report whether it's an 24 aggressive cancer or not? 25 A. It would give you more information. I --</p>	<p style="text-align: right;">Page 128</p> <p>1 your -- I mean, have you studied tissue biopsies of 2 cancers or is this something that you're -- kind of 3 have more general expertise in? 4 A. This is something as a hospitalist I'm 5 familiar with how patient care, the process of 6 patient care involves tissue biopsy in order to 7 prognosticate and in order to make treatment 8 decisions and in order to diagnose. 9 Q. Got it. 10 It's not something that you do as -- on 11 a -- on a regular basis? 12 A. I don't -- if you could clarify what you 13 mean by what I do, so I don't -- I'm not a 14 pathologist. I'm a hospitalist. 15 As a hospitalist you do kind of make plans 16 to get a biopsy and do -- use the results of the 17 biopsy for decisions. You often do this in concert 18 with other experts such as oncologists. So I -- I'm 19 familiar with how they're used with the caveats that 20 I just told you. 21 Q. Got it. 22 I think, you know, I've asked you and 23 you've told me now several times about, you know, 24 general causation or lack thereof with respect to 25 your opinion.</p>
<p style="text-align: right;">Page 127</p> <p>1 again, that would depend on the characteristics of 2 the pathology test. And the pathology test is 3 probably the best you can know up until that point 4 without kind of foresight into the future. 5 But I would have to review the 6 characteristics of the pathology test and the 7 epidemiology associated with different histologies 8 that you might find on the pathology test. 9 Q. So fair to say that without foresight in 10 the future you're not going to know the answer, I 11 mean, and nobody has a crystal ball with that 12 foresight to know if -- if that particular tissue 13 biopsy represents an aggressive or less aggressive 14 form of prostate cancer? 15 A. I think it's fair to say we don't know 16 with a hundred percent certainty. But I -- I would 17 have to review the evidence to tell you how much 18 uncertainty there is with a tissue biopsy. 19 Q. How much uncertainty as to? 20 A. The aggressiveness of the cancer or the 21 life expectancy -- 22 Q. Got it. 23 A. -- of the patient. 24 Q. Got it. Got it. 25 Is that something that you have done in</p>	<p style="text-align: right;">Page 129</p> <p>1 I want to ask you about the -- the -- the 2 threshold that the plaintiffs have placed in their 3 class definition. 4 Have you -- have you reviewed that 5 threshold, lifetime cumulative threshold that's in 6 the third amended complaint? 7 MR. STOY: Object to the form. 8 THE WITNESS: Have I reviewed the 9 threshold, is your question? 10 BY MR. MIGLIACCIO: 11 Q. Yes. Yep. 12 A. I'm familiar with the statement of some 13 threshold in the acronym lifetime -- LCT, lifetime 14 cumulative threshold. 15 Q. Got it. 16 Are you offering any opinions with respect 17 to that threshold? 18 MR. STOY: Object to the form. 19 BY MR. MIGLIACCIO: 20 Q. Or LCT? 21 A. I'm offering opinions on whether that 22 threshold is feasible to assess. 23 Q. In what -- in what way? 24 A. In the sense that in my report I describe 25 a number of different sources of cancer, a number of</p>

<p style="text-align: right;">Page 130</p> <p>1 different sources of nitrosamines, not just affected 2 valsartan, but potentially other drugs and other 3 dietary sources, and endogenous production of 4 nitrosamines. 5 And in my report an opinion of mine is 6 that it would be difficult to assess whether 7 somebody has passed the lifetime cumulative 8 threshold. Aside from the question of whether the 9 lifetime cumulative threshold is actually a valid 10 concept. 11 Q. Do you understand that the lifetime 12 cumulative threshold set forth by the plaintiffs 13 defines a risk or exposure floor? 14 MR. STOY: Object to the form to the 15 extent it assumes facts not on the record. 16 Go ahead. 17 THE WITNESS: Frank, I can barely hear 18 you. 19 MR. STOY: I'm sorry. 20 I made an objection to form to the extent 21 it assumes facts not on the record. I'll speak up. 22 THE WITNESS: Okay. 23 And, Nick, can I hear you ask the question 24 again? 25</p>	<p style="text-align: right;">Page 132</p> <p>1 we haven't answered that yet, then I'm not sure how 2 we even know a lower bound on the -- on the causal 3 effect of nitrosamines on cancer. 4 BY MR. MIGLIACCIO: 5 Q. I -- I was asking you to assume that. But 6 that -- that's -- I'm asking you to make that 7 assumption. 8 A. Okay. Sure. 9 Q. Yeah. 10 Then do you understand that it would set 11 a -- a floor, an -- a floor, a risk floor? 12 MR. STOY: Same objections. 13 THE WITNESS: Well, under the assumption 14 that we have a lower bound, then by construction it 15 does set a floor. 16 BY MR. MIGLIACCIO: 17 Q. Got it. 18 How -- I want to ask you some questions 19 about pricing, which I -- I think you detailed 20 elsewhere in -- in your report. I think you use an 21 example of Massachusetts General as one of the 22 hospitals. I think Dr. Song might be associated 23 with Massachusetts General. 24 A. We all love MGH. 25 Q. Yeah. Yeah, yeah.</p>
<p style="text-align: right;">Page 131</p> <p>1 BY MR. MIGLIACCIO: 2 Q. Yes. 3 I mean, do you understand that the 4 lifetime cumulative threshold set forth by the 5 plaintiffs defines a risk or exposure floor, that 6 it's a floor? 7 A. I'm not sure I understand that because, 8 again, I'm not an expert on causation. But if it's 9 possible that nitrosamines don't cause cancer, then 10 I'm not sure how it would set a floor unless if the 11 floor includes zero. 12 Q. Got it. 13 And if it's possible, let's just say 14 for -- hypothetically, for your purposes, I guess, 15 that nitrosamines do cause cancer and that the -- 16 the threshold and the system, the scoring system set 17 forth by the plaintiffs details how much nitrosamine 18 is in a particular dosage, would -- then would you 19 understand that -- that it would set a floor? 20 MR. STOY: Objection. Incomplete 21 hypothetical. 22 Go ahead. 23 THE WITNESS: I'm not sure how that would 24 be done. If -- first you -- as you say, you would 25 need to say that nitrosamines do cause cancer. If</p>	<p style="text-align: right;">Page 133</p> <p>1 Do you know Dr. Song? 2 A. I -- I do. 3 Q. You do. Yeah. 4 A. Yeah. 5 Q. Yeah, I can't imagine there are that many 6 MD-Ph.D. experts out there in the world. Probably a 7 very small number, I guess. 8 A. Yeah. I think less than 20 probably. 9 Q. Wow, wow, wow. 10 So my question about MGH, I mean, is it 11 fair to say that MGH has a -- has a lot of market 12 power? 13 MR. STOY: Object to the form. 14 THE WITNESS: I'm not sure exactly how I 15 would characterize it, but I know that MGH has been 16 involved in litigation regarding its market power. 17 BY MR. MIGLIACCIO: 18 Q. Okay. Did you have any involvement in 19 that? 20 A. No. 21 Q. Let me -- I mean, I think we've taken a 22 break. I'm not -- I do want to go back to one of 23 the -- you know, I want to about explore a little 24 bit more this question of -- of your -- your 25 testimony in the -- in the -- in the opioid</p>

<p style="text-align: right;">Page 134</p> <p>1 litigation.</p> <p>2 You know, Frank can obviously object if --</p> <p>3 as -- as necessary, but I did want to see if you</p> <p>4 could testify more about, you know, the subject</p> <p>5 about -- you know, the subject matter in a general</p> <p>6 matter.</p> <p>7 A. More about what? Sorry?</p> <p>8 Q. The subject matter of that litigation in</p> <p>9 a -- in a general matter, if you could give us that</p> <p>10 in -- in a general matter without divulging any</p> <p>11 confidential information?</p> <p>12 MR. STOY: I -- I think the challenge</p> <p>13 there, Nick, is with a question that broad he might</p> <p>14 not be comfortable answering it because he's not</p> <p>15 sure where those lines are, right.</p> <p>16 MR. MIGLIACCIO: Uh-huh.</p> <p>17 MR. STOY: A more specific question he</p> <p>18 might be able to give you a specific answer.</p> <p>19 MR. MIGLIACCIO: Well, how -- let me try</p> <p>20 to -- I'll try to narrow it down a little bit.</p> <p>21 Q. Can you tell us how the testimony in those</p> <p>22 cases is similar to the testimony you're offering</p> <p>23 here?</p> <p>24 A. Sort of -- like thematically, is that --</p> <p>25 is that your question?</p>	<p style="text-align: right;">Page 136</p> <p>1 transcripts exist.</p> <p>2 THE WITNESS: Oh.</p> <p>3 BY MR. MIGLIACCIO:</p> <p>4 Q. That's what I'm asking.</p> <p>5 A. Yeah. Yeah, transcripts exist.</p> <p>6 Q. They do exist, okay.</p> <p>7 And do you know, are they -- do you know</p> <p>8 if they are marked confidential or not in their</p> <p>9 entirety?</p> <p>10 A. I don't know.</p> <p>11 Q. Okay. Got it.</p> <p>12 Is that litigation currently ongoing? Can</p> <p>13 you answer that question?</p> <p>14 A. I am not sure. I think so.</p> <p>15 Q. Okay. I'm not -- I don't want to ask you</p> <p>16 anything about it. Just if it -- okay. Okay.</p> <p>17 So going back to -- to this question on,</p> <p>18 you know, Massachusetts General's market power or --</p> <p>19 or -- you know, is it fair to say that the prices in</p> <p>20 one area of the country can, you know, differ in --</p> <p>21 for instance, Massachusetts General may have high</p> <p>22 prices, but if you go to rural western Massachusetts</p> <p>23 the prices would be lower, of medical care, medical</p> <p>24 services?</p> <p>25 A. It's fair to say that prices differ a lot</p>
<p style="text-align: right;">Page 135</p> <p>1 Q. Thematically or subject matter. You know,</p> <p>2 is the subject matter similar. Both of those</p> <p>3 questions, thematically and subject matter.</p> <p>4 MR. STOY: Dr. Chan, if you can ask -- if</p> <p>5 you can answer that question from a high level, I</p> <p>6 think it's okay. So that would be my instruction to</p> <p>7 you.</p> <p>8 THE WITNESS: From a high level, I am</p> <p>9 relying on my expertise as an economist, as a</p> <p>10 clinician, and as somebody who is familiar with</p> <p>11 health policy.</p> <p>12 BY MR. MIGLIACCIO:</p> <p>13 Q. Do -- can -- did those other cases, do</p> <p>14 they involve class action claims?</p> <p>15 A. No.</p> <p>16 Q. There are transcripts of those</p> <p>17 depositions, is that right, the ones that you</p> <p>18 took -- that you gave?</p> <p>19 THE WITNESS: Sorry. Go -- go ahead,</p> <p>20 Frank.</p> <p>21 MR. STOY: No, you can answer that. Go</p> <p>22 ahead.</p> <p>23 THE WITNESS: I don't know if the</p> <p>24 transcripts are public, in the public domain.</p> <p>25 MR. STOY: He just asked you if</p>	<p style="text-align: right;">Page 137</p> <p>1 across different hospitals and different payors. I</p> <p>2 am not sure if your prediction is true where</p> <p>3 Massachusetts General would necessarily have higher</p> <p>4 prices than western Massachusetts.</p> <p>5 And I think part of the analyses that I</p> <p>6 lay out is not just to show the average price of</p> <p>7 Massachusetts General Hospital but that even within</p> <p>8 the same hospital, there is wide variation across</p> <p>9 different payors.</p> <p>10 Q. Uh-huh. And you know about that wide</p> <p>11 variation, right? I mean, you -- you have data that</p> <p>12 demonstrates it?</p> <p>13 A. Correct.</p> <p>14 Q. So is it fair to say that that variation</p> <p>15 is knowable?</p> <p>16 MR. STOY: Object to the form.</p> <p>17 THE WITNESS: Some of the variation's</p> <p>18 knowable. With respect to this class, it's likely</p> <p>19 that we might not know as researchers or as, you</p> <p>20 know, using publicly available data, what the</p> <p>21 relevant price would be for the members of the</p> <p>22 class.</p> <p>23 BY MR. MIGLIACCIO:</p> <p>24 Q. You're talking about the proposed class</p> <p>25 here in this case?</p>

<p style="text-align: right;">Page 138</p> <p>1 A. Correct.</p> <p>2 Q. And you know -- I mean, you know, you</p> <p>3 understand that this class has not been finally</p> <p>4 certified yet, right?</p> <p>5 A. Correct.</p> <p>6 Q. So there -- it's not -- you know,</p> <p>7 there's -- there is not yet a defined class and the</p> <p>8 definition could potentially be different than the</p> <p>9 way it is presently, correct?</p> <p>10 A. Correct.</p> <p>11 The reason I answered the question that</p> <p>12 way is because what we know about Massachusetts</p> <p>13 General Hospital -- first of all, this is a recent</p> <p>14 development within the year that we required</p> <p>15 hospitals to be more transparent about their prices.</p> <p>16 There is still uncertainty about whether there's</p> <p>17 full transparency about the prices and furthermore,</p> <p>18 we only know prices in the hospital setting. We</p> <p>19 don't know prices in the outpatient setting. So</p> <p>20 there is still big gaps in what we know.</p> <p>21 Q. Tell me about this recent development that</p> <p>22 just happened with respect to -- that you just</p> <p>23 referenced.</p> <p>24 A. I believe that in the last year or so the</p> <p>25 government mandated hospitals to be more transparent</p>	<p style="text-align: right;">Page 140</p> <p>1 certain services but out of network for other</p> <p>2 services because the hospital might employ different</p> <p>3 people and they might not know what prices they're</p> <p>4 going to get.</p> <p>5 So I think surprise billing is</p> <p>6 specifically about the question about whether</p> <p>7 they're in -- whether they're in network or out of</p> <p>8 network, and there could be huge differences in</p> <p>9 prices faced that are unexpected by patients as a</p> <p>10 result of that.</p> <p>11 Q. Got it. Got it.</p> <p>12 So you think that the government --</p> <p>13 that -- that the government has started with</p> <p>14 hospitals as -- as -- as a first priority, but it</p> <p>15 may not have moved to outpatient procedures yet?</p> <p>16 A. It has not. It has not moved to</p> <p>17 outpatient procedures.</p> <p>18 Q. It has not.</p> <p>19 And do you know when of if it will move to</p> <p>20 outpatient procedures?</p> <p>21 A. I don't. It's -- I was -- we, you know, I</p> <p>22 don't think most people saw that the Trump</p> <p>23 Administration would make price transparency a</p> <p>24 priority and now we might have other priorities and</p> <p>25 it's unclear.</p>
<p style="text-align: right;">Page 139</p> <p>1 with their prices and the reason it did that was</p> <p>2 because it was well known that there was a lot of</p> <p>3 intransparency in what prices would be if a patient</p> <p>4 kind of walked into the emergency department at</p> <p>5 Massachusetts General and got a procedure, there</p> <p>6 could be tenfold, maybe even a hundredfold</p> <p>7 difference in kind of prices depending on where they</p> <p>8 went and what provider -- what insurer they had.</p> <p>9 There was just huge amount of</p> <p>10 intransparency and uncertainty from patients'</p> <p>11 perspectives. The government decided to make that a</p> <p>12 priority and it started with hospitals, for</p> <p>13 hospitals to make prices more transparent.</p> <p>14 Q. This was legislation, right, like federal</p> <p>15 legislation?</p> <p>16 A. I don't know if it's legislation or an</p> <p>17 executive order.</p> <p>18 Q. Okay. And are you talking about -- I</p> <p>19 mean, I've heard of something called surprise</p> <p>20 billing. Is that related to -- to what you're</p> <p>21 talking about now?</p> <p>22 A. It's potentially -- it's related. It's</p> <p>23 not exactly the same. Surprise billing is another</p> <p>24 whole level of complexity where somebody can go to</p> <p>25 the hospital and they could be in network for</p>	<p style="text-align: right;">Page 141</p> <p>1 They've been intransparent for decades.</p> <p>2 They suddenly became transparent in this one kind of</p> <p>3 sector of the healthcare industry. Who knows what's</p> <p>4 going to happen in the future.</p> <p>5 Q. When did this happen, like when did the --</p> <p>6 just January 1 of this year?</p> <p>7 A. Within the year, within 2020 -- or</p> <p>8 actually, 2021. I'm not -- I would have to review</p> <p>9 the dates of this.</p> <p>10 Q. Sure.</p> <p>11 And -- and you think it was an executive</p> <p>12 order that did it?</p> <p>13 A. It -- it could have been an executive</p> <p>14 order.</p> <p>15 Q. Okay.</p> <p>16 A. I'm not sure.</p> <p>17 Q. Got it.</p> <p>18 Yeah, I -- I won't hold you to it. We</p> <p>19 could look at it and figure it out exactly if</p> <p>20 necessary.</p> <p>21 A. Yes.</p> <p>22 Q. How does that change or -- your analysis</p> <p>23 in your report or does it because since this sector</p> <p>24 now has great -- great transparency?</p> <p>25 MR. STOY: Object to the form.</p>

<p style="text-align: right;">Page 142</p> <p>1 THE WITNESS: I -- I don't know if I'd 2 characterize it as great transparency. Again, 3 it's -- it's a part of the healthcare -- it's a -- 4 it's a sub -- subset of providers that work in 5 hospitals that are now required to disclose prices 6 with various insurers. We don't know whether this 7 information is accurate yet. It's only been out 8 there for a little while.</p> <p>9 There is a vast majority -- there's a lot 10 of other places that patients get care, most of the 11 time in outpatient settings, that we still don't 12 know what those prices are.</p> <p>13 BY MR. MIGLIACCIO: 14 Q. Are you doing any research into this, like 15 is this part of your academic research?</p> <p>16 A. This is not -- it's not currently a part 17 of my research agenda. It's certainly within my 18 scope of expertise, and I could become interested in 19 it at some later point.</p> <p>20 Q. Yeah. Has -- have the -- has the first 21 dataset become available?</p> <p>22 A. They are available on the -- on -- I 23 believe they're -- they're required to make the 24 datasets available. If you look at, for example, 25 figure -- where I have like the prices at</p>	<p style="text-align: right;">Page 144</p> <p>1 done by a hospital. So it's, for example, a clinic 2 that is associated with MGH.</p> <p>3 Q. Okay. So -- so I'm in Washington, D.C. 4 And I'm just going to, you know, give you a -- like 5 kind of an example of how it is here.</p> <p>6 MedStar is a big hospital system in the 7 Washington, D.C. area.</p> <p>8 A. Uh-huh.</p> <p>9 Q. And if you go to a physician -- as an 10 outpatient, there are many physicians now, it seems 11 to me, that are like the MedStar, you know, office 12 of a certain specialty, but they're an outpatient 13 clinic.</p> <p>14 Does Massachusetts General have outpatient 15 clinics that do things like urinalysis, 16 colonoscopies, et cetera?</p> <p>17 A. Yes.</p> <p>18 Q. Okay. And they're like branded as 19 Massachusetts General, you know, GI specialists? 20 I'm giving a hypothetical, fictional example, but is 21 that a realistic sort of thing?</p> <p>22 A. That -- that possibility does -- does 23 exist where --</p> <p>24 Q. Okay.</p> <p>25 A. -- there's a clinic that is I believe</p>
<p style="text-align: right;">Page 143</p> <p>1 Massachusetts General --</p> <p>2 Q. Uh-huh.</p> <p>3 A. -- there is a note that tells you where to 4 download those data.</p> <p>5 Q. Uh-huh.</p> <p>6 A. So Figure 8 is where you would look for 7 MGH. And I would imagine that other hospitals have 8 other sites where you could download their data.</p> <p>9 Q. Got it.</p> <p>10 So you got this from that -- from that 11 database?</p> <p>12 A. Correct.</p> <p>13 Q. That's where this came from. Got it.</p> <p>14 And had it relates to -- and so the -- 15 the -- the CPT HCPS -- HP -- HCPCS code --</p> <p>16 A. You can call it -- you can call it 17 "hick-picks."</p> <p>18 Q. "Hick-picks"? Did I say that right?</p> <p>19 A. Yes.</p> <p>20 Q. "Hick-picks." Got it. Okay. Thanks.</p> <p>21 Those codes, so these would be procedures 22 that were done inpatient; is that right?</p> <p>23 A. These are procedures --</p> <p>24 Q. Oh, outpatient. Outpatient. Sorry.</p> <p>25 A. Right. They're outpatient but they're</p>	<p style="text-align: right;">Page 145</p> <p>1 owned by MGH and submits claims under the 2 Massachusetts General Hospital tax ID, there are 3 examples of that.</p> <p>4 Q. Okay. And so the pricing of all these 5 clinics -- or of that particular hypothetical, 6 fictional, potentially, you know, fictional clinic, 7 would be transparent now in this matter?</p> <p>8 MR. STOY: Object to the form to the 9 extent it misstates his prior testimony. Objection. 10 Incomplete hypothetical.</p> <p>11 THE WITNESS: You want to restate your 12 question? You had a lot of fictional, hypothetical 13 in there.</p> <p>14 BY MR. MIGLIACCIO: 15 Q. Sure.</p> <p>16 I mean, so let's say there's an MGH 17 outpatient clinic that does colonoscopies. The 18 prices of those colonoscopies are now going to be 19 known?</p> <p>20 MR. STOY: Object to the form. Same 21 objection.</p> <p>22 THE WITNESS: It's unclear whether we 23 actually do know the prices.</p> <p>24 I also want to say that we -- I'm not sure 25 if we know all of the -- you know, it's -- it's</p>

<p style="text-align: right;">Page 146</p> <p>1 helpful to circle back to this class, and I believe 2 the class are the patients here. 3 So we would be interested in what the 4 patients would pay, not necessarily the price that 5 the provider is getting. I don't know if we know 6 all of the details of the insurance contract. I 7 know that this price transparency, it could be 8 limited to just the price that the provider is 9 getting between the provider and the insurance 10 company. 11 It does not give you information on cost 12 sharing in this insurance contract between the 13 patient and the -- and -- and the insurer. And as I 14 just mentioned, we don't know the quality of this 15 data yet. These data yet. 16 BY MR. MIGLIACCIO: 17 Q. But you've used it in your report, at 18 least in Figure 8? 19 A. Yes. Because we can see that even if the 20 quality was off, even if we didn't have the price 21 exactly right, it does show quite a bit of 22 variation. And that variation is illustrative. 23 There's other sources of research out there even 24 before this price transparency. 25 This, you know, within the last year that</p>	<p style="text-align: right;">Page 148</p> <p>1 Q. It's on page 69. 2 A. Uh-huh. 3 Q. Is that the announcement of this -- 4 this -- this new transparency requirement? 5 A. Possibly. Although this is a little bit 6 earlier than I thought it would be. 7 Q. Okay. Yeah, that's why I was asking 8 because I don't know. 9 A. It's possible. 10 Q. All right. Got it. Okay. I mean -- 11 yeah. 12 Do you -- with respect to -- to the -- 13 this issue that you just raised of pricing the -- 14 the split between what the patient pays and what the 15 insurer pays, do you understand that Dr. Song's 16 report focuses on estimating total price, not just 17 the patient's share of the price? 18 A. That was a little confusing to me, as I 19 understood the complaint to be the -- to be the cost 20 that the patient would bear, not total price. But I 21 did notice that in Dr. Song's report he didn't delve 22 into issues of cost sharing. 23 Q. So would -- would -- would it change your 24 opinion now if you understood that he is only 25 focusing on estimating the total price and not just</p>
<p style="text-align: right;">Page 147</p> <p>1 has demonstrated large variation in prices within 2 insurer, within provider, kind of looking at the 3 intersection between providers and insurers. It's 4 a -- it's a -- it's a research finding as of five, 5 six years ago that there is huge variation in price 6 across different private insurers and private -- and 7 providers. 8 Q. How -- do you know if there has been any 9 research done to determine whether the price -- 10 pricing data is -- is inaccurate? 11 MR. STOY: Object to the form. 12 THE WITNESS: This is something that 13 people are currently looking at. I think it's still 14 pretty new for us to know. 15 BY MR. MIGLIACCIO: 16 Q. It's required by federal law, right, and 17 this is not something that's being done voluntary, I 18 imagine? 19 A. That's right. This new -- at least what I 20 just -- by it, what I just discussed about hospitals 21 publishing data on prices for various procedures and 22 various payors. 23 Q. I'm looking at footnote 207 of your 24 report. Can you -- 25 A. Okay.</p>	<p style="text-align: right;">Page 149</p> <p>1 the payment -- patient share of the price? 2 A. I understand what he's doing, but my 3 understanding of the class is that we are interested 4 in what patients would bear. So I was a bit 5 confused. It seemed to me that that was an omission 6 in the analysis that he did. 7 Q. Is it fair to say that the total price is 8 the more appropriate measure for the burden borne by 9 society for -- for testing? 10 MR. STOY: Object to the form. 11 THE WITNESS: I think that would be a much 12 more complicated question. The burden borne by 13 society. I don't think that total price is a good 14 measure of that either because that includes profits 15 by hospitals and like charges versus what they 16 actually get after negotiations. There is just a 17 lot of additional complexity there. I think burden 18 borne to society would have to be better defined. 19 BY MR. MIGLIACCIO: 20 Q. All right. I'll give you some -- just 21 some -- I'll set this up with some hypothetical 22 questions for you. 23 Let's say there is a person at risk of 24 developing cancer, you know, as a result of a 25 medication contaminated with a carcinogen, right.</p>

<p>Page 150</p> <p>1 Let -- let's assume all those things are -- are 2 true. There's somebody who took a -- you know, 3 ingested a carcinogen and they are at a risk -- a 4 higher risk of developing cancer. 5 Can -- do you follow that? 6 A. Yes. 7 Q. Okay. Who in society should bear the 8 burden for screening that person for cancer risks? 9 MR. STOY: Objection. Incomplete 10 hypothetical. Objection to the extent it calls for 11 a legal conclusion. 12 You can go ahead. 13 THE WITNESS: Your question is who -- if 14 there is a pill that somebody ingested that puts 15 them at higher risk for cancer, who should be 16 responsible for bearing that burden? 17 I don't think that's within the scope of 18 my report. I don't know if that's within my 19 expertise to say who should be responsible for that. 20 BY MR. MIGLIACCIO: 21 Q. As a healthcare economist, what -- does 22 your research focus or include expertise on who 23 should pay what in -- in the healthcare system? 24 MR. STOY: Object to the form. 25 THE WITNESS: No. By "should," do you</p> <p>Page 151</p> <p>1 mean some normative sense of who bears 2 responsibility, who should -- as an economist, I 3 think that would take a lot of careful thinking. We 4 might have the tools to consider that but I wouldn't 5 have the tools to think about it right off the bat 6 on this call. 7 We often -- it depends on contracts. It 8 depends on the legal system. We use -- we are quite 9 familiar with contracts and who does pay the burden 10 and we might compare different contracting 11 arrangements and compare which one is better in 12 terms of welfare for society. But those would be 13 complicated analyses that would take deeper thought. 14 BY MR. MIGLIACCIO: 15 Q. In the current regime we have in this 16 country for healthcare -- for healthcare generally, 17 who pays for healthcare for an -- an average person? 18 Maybe that -- maybe that's too difficult for you -- 19 you know, a hypothetical person, let's give it a 20 hypothetical person. 21 MR. STOY: Object to the form. 22 THE WITNESS: Yeah. 23 MR. STOY: Objection. Incomplete 24 hypothetical. 25 (Whereupon, a brief discussion off the</p>	<p>Page 152</p> <p>1 record.) 2 THE WITNESS: I was -- I was starting the 3 shortest answer is that it's complicated. It 4 depends on the person. It changes year to year 5 depending on healthcare reform or not. There are 6 just so many variables to consider here I don't 7 think I could give you an answer that would fit 8 within my seven hours probably. 9 BY MR. MIGLIACCIO: 10 Q. Yeah. Let me try to -- let me try to put 11 some specificity around this and see if we can fit 12 within the seven hours. 13 Medicare. Who -- who -- who's eligible in 14 this country? 15 A. Broadly speaking, there are two types of 16 people that are eligible for Medicare. People that 17 are above 65 and people with some disability. There 18 are also special populations such as people that 19 have renal failure and get dialysis. 20 Q. Let's say somebody's over the age of 65, 21 right, they're eligible for Medicare. 22 Who pays for Medicare for that person who 23 is eligible for it? 24 A. There are several levels to this. 25 Medicare is a government program so the government</p> <p>Page 153</p> <p>1 runs -- the government funds Medicare through 2 taxpayer dollars. There are -- again, I could give 3 you a longer answer, but I think the shorter answer 4 is that it's a government-run program that is funded 5 by taxpayer dollars and administered by private 6 contractors. 7 So who pays, it could be like any of 8 those, it could be the taxpayers, it could be the 9 government, or it could be the private contractors 10 that administer Medicare in different jurisdictions. 11 Q. Where does the money ultimately come from? 12 MR. STOY: Object to the form. 13 BY MR. MIGLIACCIO: 14 Q. For that person's healthcare? 15 A. As I said, it -- you know, one way to 16 trace it back is, you know, taxpayers fund the 17 Medicare program. 18 Q. Yeah. Got it. 19 So if there is a person -- strike that. 20 I'll -- I'll ask it a different way. 21 Have you done any research into -- I think 22 you were -- you had talked about the research you've 23 done with diagnoses and trying -- and I don't want 24 to misstate it. What was that research again? 25 A. It was research on the diagnostic process,</p>
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1 the -- yeah, I think I would just succinctly sum it
2 up as the research on the diagnostic process.
3 Q. And then that related to Afib, right,
4 atrial fibrillation, or was that a different?
5 A. The guidelines research is related to
6 atrial fibrillation.
7 Q. Got it.
8 What are the --
9 A. Go ahead.
10 Q. What -- what are the risks associated with
11 some -- with -- with an individual or a patient
12 population who does not get timely treatment for
13 atrial fibrillation?
14 MR. STOY: Object to the form.
15 THE WITNESS: Your question was whether --
16 what are the risks for patients that don't get
17 timely treatment for atrial fibrillation.
18 I think this is actually -- so I was going
19 to say that my research on diagnoses is not
20 necessarily the research on atrial fibrillation.
21 The research on atrial fibrillation is my research
22 on guidelines. Timeliness of diagnosis is not
23 really an issue with atrial fibrillation.
24 Atrial fibrillation's a chronic condition.
25 Most people have it, you know, by the time they're

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1 very old. And the question here is how you should
2 treat atrial fibrillation, not whether you should
3 diagnose it or how do you diagnose it.
4 BY MR. MIGLIACCIO:
5 Q. Got it.
6 The research you did on diagnoses, were
7 those for any particular disease? Did they focus on
8 anything specific?
9 A. The research is motivated very broadly.
10 The paper where I dig into a specific clinical
11 setting in depth is in the presentation of patients
12 in the emergency department with potential
13 pneumonia.
14 Q. And what was your conclusion there?
15 A. That there are real possibilities of
16 Type I and Type II error in the diagnosis process.
17 That there are questions about how many people we
18 should diagnose or not.
19 But more importantly, there are questions
20 about diagnostic accuracy. You could diagnose the
21 same number of people but have a much higher
22 accuracy in doing so. And that the diagnostic
23 process is not just a simple test like a chest x-ray
24 but it also involves human interpretation and
25 involves a system of care that could be prone to

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1 error.
2 Q. Got it.
3 With respect to pricing, is it fair to say
4 that industry and government agencies use averages
5 for pricing certain things? I'll say, for instance,
6 gasoline?
7 MR. STOY: Object to the form. Objection
8 beyond -- to the extent it's beyond the scope.
9 THE WITNESS: Do you want to be more
10 specific about how they use the averages?
11 BY MR. MIGLIACCIO:
12 Q. Well, even if there is variation in the
13 real world, I mean, doesn't -- can't you determine
14 the average price of gasoline?
15 A. I think the question is whether the
16 average price of gasoline, in this case the average
17 price of a service used in screening, is the
18 relevant object.
19 Of course you can calculate an average but
20 the question you should ask is whether it's the
21 right average for the right patient population and
22 whether it's the only thing that matters.
23 Obviously, we -- we measure standard
24 deviation in variants in a lot of settings because
25 we care about variation. So the question is not

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1 whether we can measure an average, but it's whether
2 that average is the right measure for what we want
3 to do.
4 Q. Uh-huh. You use averages in your own
5 work; isn't that fair to say?
6 MR. STOY: Object to the form.
7 THE WITNESS: Again, the question is what
8 average am I using. You know, if you're using an
9 average in your research paper, you have to defend
10 that that's the right average, that that's the
11 average that we care about. And you -- if you're
12 not, you should expect pushback from your peers
13 about whether you're using the right average or not.
14 BY MR. MIGLIACCIO:
15 Q. Can you give me some examples of where
16 you've used an average and where you've had pushback
17 and where you've defended it?
18 MR. STOY: Object to the form. Objection.
19 Beyond the scope of his report.
20 THE WITNESS: I can't remember the last
21 time I personally got pushback, but I could imagine
22 getting pushback if you are saying that you're
23 interested in one patient population and you're
24 giving the average for another patient population.
25

<p style="text-align: right;">Page 158</p> <p>1 BY MR. MIGLIACCIO:</p> <p>2 Q. Got it.</p> <p>3 So like two distinct patient populations.</p> <p>4 What would be an example of like one patient</p> <p>5 population and an average for a different one? Can</p> <p>6 you -- can you give me one?</p> <p>7 A. Yes, I think in this case it would be the</p> <p>8 average -- if you're using the average price -- the</p> <p>9 private insurance price for some general patient</p> <p>10 population that isn't well defined and you're</p> <p>11 applying that to the patients that took at-issue</p> <p>12 valsartan. Those would be two different patient</p> <p>13 populations.</p> <p>14 Q. I think you stated in your report that</p> <p>15 the -- when you looked at some of the data, that you</p> <p>16 saw the average age of a valsartan -- of somebody</p> <p>17 who took one of the valsartan-containing drugs was</p> <p>18 63 years old.</p> <p>19 Do you remember that?</p> <p>20 A. Yes, I do. I would have to look...</p> <p>21 Q. Yeah, I'll -- I see that.</p> <p>22 MR. STOY: And, Nick, while he's</p> <p>23 looking --</p> <p>24 MR. MIGLIACCIO: Yeah.</p> <p>25 MR. STOY: -- we're coming up on noon</p>	<p style="text-align: right;">Page 160</p> <p>1 record. The time is 12:36 p.m.</p> <p>2 BY MR. MIGLIACCIO:</p> <p>3 Q. All right. Dr. Chan, I want to ask you a</p> <p>4 few questions.</p> <p>5 I want to go back to paragraph 42 briefly</p> <p>6 of your report. And you have -- I think you detail</p> <p>7 Figure 2 and discuss risk factors for specific</p> <p>8 populations.</p> <p>9 A. Okay.</p> <p>10 Q. I think I'm going to read the last</p> <p>11 sentence of paragraph 42 which states, "Even with</p> <p>12 these substantial relative risks, again, only age</p> <p>13 and smoking history are used to define the specific</p> <p>14 population recommended for colorectal and lung</p> <p>15 cancer screening."</p> <p>16 Did you detail the relative risk of age</p> <p>17 for colorectal cancer in this paragraph?</p> <p>18 A. Not in this in paragraph. It might be</p> <p>19 detailed somewhere else in the report, but I can't</p> <p>20 find it right now.</p> <p>21 Q. Okay. All right.</p> <p>22 Yeah, well I couldn't find it either so,</p> <p>23 you know, I -- if we have more time I might ask you</p> <p>24 to look and see or at least tell me where it can be</p> <p>25 found.</p>
<p style="text-align: right;">Page 159</p> <p>1 Dr. Chan's time so just --</p> <p>2 MR. MIGLIACCIO: Yeah.</p> <p>3 MR. STOY: -- keep that in mind.</p> <p>4 MR. MIGLIACCIO: Sure. Are you hungry,</p> <p>5 Dr. Chan, if you want to eat something, please just</p> <p>6 say the word because I was starving before and I</p> <p>7 don't want you --</p> <p>8 THE WITNESS: I could -- I could certainly</p> <p>9 eat, yeah. I could definitely eat.</p> <p>10 MR. MIGLIACCIO: Please do. We could</p> <p>11 take -- we could take a break.</p> <p>12 THE WITNESS: Okay.</p> <p>13 MR. MIGLIACCIO: Yeah.</p> <p>14 THE WITNESS: You want to do 30 minutes?</p> <p>15 MR. MIGLIACCIO: That's fine with me.</p> <p>16 MR. STOY: Will that be okay with the</p> <p>17 overall time constraints, Nick?</p> <p>18 MR. MIGLIACCIO: I think so. I -- I</p> <p>19 really -- I do. And I'm -- because I think even</p> <p>20 from now we have like five hours and I think --</p> <p>21 MS. HILTON: Can we go off the record?</p> <p>22 THE VIDEOGRAPHER: We're off the record at</p> <p>23 11:56 a.m. Pacific time.</p> <p>24 (Whereupon, a brief recess was taken.)</p> <p>25 THE VIDEOGRAPHER: We are back on the</p>	<p style="text-align: right;">Page 161</p> <p>1 A. Yeah.</p> <p>2 Q. Because I did not see it myself.</p> <p>3 But in the meantime, I will go back and</p> <p>4 ask you some other questions.</p> <p>5 We were talking, I think, before the break</p> <p>6 about pricing of medical services and -- you know, I</p> <p>7 want to ask you about Dr. Song. If you would agree</p> <p>8 that he's qualified to offer the opinions that he</p> <p>9 has offered?</p> <p>10 MR. STOY: Object to the form. Objection</p> <p>11 to the extent it calls for a legal conclusion with</p> <p>12 regard to qualifying Dr. Song as an expert.</p> <p>13 THE WITNESS: Yeah, I'm not sure if I can</p> <p>14 qualify -- I'm qualified to assess whether he's</p> <p>15 qualified.</p> <p>16 BY MR. MIGLIACCIO:</p> <p>17 Q. Would you agree he's well respected in the</p> <p>18 field?</p> <p>19 MR. STOY: Object to form.</p> <p>20 THE WITNESS: I'm -- I'm not sure how to</p> <p>21 characterize that. I know him.</p> <p>22 BY MR. MIGLIACCIO:</p> <p>23 Q. Okay. Have you ever cited his work in any</p> <p>24 of your own publications?</p> <p>25 A. I'm not sure if I have.</p>

<p style="text-align: right;">Page 162</p> <p>1 Q. Would you agree that the publications that 2 Dr. Song relied upon are well accepted and 3 peer-reviewed in his report? 4 MR. STOY: Object to the form. 5 THE WITNESS: I'm not sure -- can you 6 restate that again? 7 BY MR. MIGLIACCIO: 8 Q. Yeah. 9 Would you agree that the publications that 10 Dr. Song relied upon in his report, and I know 11 you've reviewed it for purposes of yours, would you 12 agree that the publications that he relied upon are 13 well accepted and peer-reviewed? 14 MR. STOY: Objection to form. 15 THE WITNESS: I don't remember going over 16 his -- the sources that he relied upon in detail. 17 And I'm not sure how I would characterize whether a 18 publication is well accepted or not. 19 BY MR. MIGLIACCIO: 20 Q. What do you recall of the -- of the 21 publications that Dr. Song relied upon? 22 A. I don't recall much. I would have to look 23 at his report again to refresh my memory. 24 Q. Okay. I can -- I think we have that. 25 Let's -- let's go get that. Bear with me. I can</p>	<p style="text-align: right;">Page 164</p> <p>1 to have lost it for the time being. 2 But would you agree with me that if -- 3 that if the average age of a valsartan user is 63, 4 and for us, and here, that the class concludes 5 several years ago, in 2018, would you agree that 6 this class, the proposed class that we have defined, 7 the majority of the class would be -- would be on 8 Medicare? Can you agree with that, if the age 9 was -- is 63 years old, the average age? 10 MR. STOY: Objection. Form. Incomplete 11 hypothetical. 12 THE WITNESS: I'm not sure if I can agree 13 with that. I think we could probably look at that 14 in more detail. But just based on these facts 15 alone, I'm not sure if that necessarily leads to 16 that conclusion. 17 BY MR. MIGLIACCIO: 18 Q. What data did you rely upon to determine 19 that the average age of a valsartan user was 20 63.3 years old? 21 A. I believe what is cited in that sentence 22 comes from another study. 23 Q. Okay. 24 A. In footnote number 87. 25 Q. Uh-huh.</p>
<p style="text-align: right;">Page 163</p> <p>1 try to pull that up for you. I'm going to try to 2 make this work on my end. So I won't -- I'll move 3 on to something while -- while I'm trying to do 4 that. 5 I'm going to ask you about some of -- of 6 your own publications. And I think I -- we had 7 discussed before the break that it's -- the average 8 age of a valsartan user was 63 years old. I think 9 we -- you -- that's what you detailed in your 10 report, right? 11 A. Yeah, I would need to look at the relevant 12 paragraph, but that sounds right, yep. 13 Q. Which paragraph was that? 14 A. I see something in paragraph 65. Is that 15 what you're referring to or... 16 Q. I think that that is what I was referring 17 to. 18 A. Okay. 19 Q. It looks to me that you -- that that data 20 was based on data that you -- 63.3 years old, right? 21 And this data was pulled in 2018; is that right? 22 A. Where do you see that it was pulled in 23 2018? 24 Q. I'm going to believe that is what I have. 25 I'm going to try to find a citation for you. I seem</p>	<p style="text-align: right;">Page 165</p> <p>1 A. And I think that would be -- it might have 2 been some summary statistics calculated in that 3 study. 4 Q. Got it. 5 Do you know if that was a meta-analysis, 6 that study? 7 A. It might have -- it likely drew from other 8 previous studies. 9 Q. Got it. Got it. 10 I'm going to show you, if I can now, 11 Dr. Song's report. And hopefully I'll be able to 12 bring it into your folder here. 13 MR. MIGLIACCIO: This will be Exhibit 4. 14 (Whereupon, Chan Exhibit 4 was marked for 15 identification.) 16 BY MR. MIGLIACCIO: 17 Q. Once I rename it. 18 A. Okay. 19 Q. You should have it now, hopefully. 20 A. Yes. 21 Q. Okay. So I had asked you about the 22 publications that he uses and used in his -- in 23 his -- in his report. I wanted to know if they were 24 authoritative, well accepted or peer-reviewed, but I 25 want -- you know, I know you've looked at this in</p>

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1 detail and it's, you know, fairly lengthy but I
 2 wanted to ask you if anything here jumps out at you
 3 as -- as being none of those things, any of the
 4 sources he cites?
 5 A. Are you asking me to refer to the
 6 materials relied upon for him?
 7 Q. Right.
 8 MR. STOY: I'm just going to put an
 9 objection on the record to -- I mean, there's over a
 10 hundred cites here, so...
 11 THE WITNESS: Yeah, I'm not sure if I'll
 12 be able to look through this and pull out any
 13 sources that don't meet those criteria. There's
 14 certainly some of these that are not peer-reviewed.
 15 And I'm not sure what you mean by
 16 authoritative and well accepted still. It's
 17 something could be very appropriate for one purpose
 18 but not very appropriate for the purposes that we
 19 require in this case.
 20 We might have a -- an article that is very
 21 appropriate when it describes the ratio of prices
 22 between private insurance and Medicare for that
 23 audience but would not be appropriate if we're
 24 trying to apply it to this case. So what you mean
 25 by well accepted and authoritative is -- depends on

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1 what you're using it for.
 2 BY MR. MIGLIACCIO:
 3 Q. Okay. Let me restate my question.
 4 A. Okay.
 5 Q. You -- you -- you reviewed his report in
 6 detail, right, in -- before you offered your
 7 opinions?
 8 A. I reviewed his report. I am not sure what
 9 you mean by "in detail." I have the hours that I
 10 reported in terms of how long I spent on reading his
 11 report.
 12 Q. You did not in your report that -- the
 13 document that you've produced, you did not identify
 14 any publications that Dr. Song relied upon that, in
 15 your mind, were suspect, did you?
 16 MR. STOY: Objection. Form.
 17 THE WITNESS: Not specific sources that I
 18 thought were suspect.
 19 BY MR. MIGLIACCIO:
 20 Q. Okay.
 21 A. But, again, some of these sources are fine
 22 for one purpose but not fine for the purposes that
 23 we need in this case and I think in my report I do
 24 describe those.
 25 Q. Which sources, and can you point me to

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1 those specifically?
 2 A. I'm not sure which paragraph I mentioned
 3 this. But I think it gets to the point of averages
 4 for a different patient population are not the
 5 averages that we want here. This has to do with
 6 needing to know how various quantities that we care
 7 about, such as prices or such as what services are
 8 going to be used, how they might correlate with
 9 patient characteristics in patients who might be in
 10 a class, and whether those data to come up with
 11 those averages even exists anywhere that anybody
 12 could use to calculate the relevant average.
 13 Q. Can you direct me to that, to that portion
 14 of your report?
 15 A. Sure. Let's see. Let me go back to my
 16 report. Now it's kind of hard -- which exhibit is
 17 it, is my report?
 18 Q. Yeah, I'm sorry, I renamed them. I
 19 believe it's Exhibit 2.
 20 A. 2. Okay. Let's see.
 21 I think paragraph 100 speaks a little to
 22 this.
 23 When you say something is correlated with
 24 something else, then you can't just calculate the
 25 average of that something else without knowing what

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1 you're conditioning on in the first place. So if
 2 something is correlated that means the average that
 3 you care about might change if you switch
 4 populations.
 5 Q. And, again, you -- you -- you do know that
 6 this population has not been determined with
 7 finality, right?
 8 A. Right. But I know that it would likely be
 9 different than the sources that Dr. Song is relying
 10 upon and I also think that it wouldn't be feasible
 11 even to measure that with the data that we have.
 12 Q. Well, why do you think it would not be
 13 feasible?
 14 A. Because the data have not been made
 15 public.
 16 Q. Which data have not been made public?
 17 A. Many of the pricing data have not been
 18 made public and how that correlates with individual
 19 characteristics of patients that would determine
 20 what services we need to recommend for the medical
 21 monitoring program. The cost sharing agreements in
 22 these contracts are not public. There are a number
 23 of different components to evaluating spending that
 24 would not be public.
 25 Q. Isn't it fair to say, though, that, you

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1 know, the government knows how much it spends
2 annually on -- on Medicare?
3 A. That, again, is an average.
4 Q. Uh-huh.
5 A. That's an overall -- that's an average for
6 how much it's spending for the entire population of
7 Medicare patients. So there's two problems with
8 that. Number one, there could be patients in the
9 class that are not Medicare patients. And number
10 two, there are Medicare patients that aren't in our
11 class.
12 Q. Right. I -- but the government
13 nonetheless can determine how much it spends for
14 the -- for the whole population, right? I mean,
15 that -- that is --
16 A. Of patients --
17 Q. -- that is --
18 A. Of patients under Medicare. But, again,
19 that's abstracting away from the possibility that we
20 care about cost sharing, which I'm still not clear
21 about if we're -- it depends on who -- you know, my
22 understanding is that the class is any -- any
23 payments that the patients would have to make for
24 monitoring, not the payor.
25 So first, that's one issue. And then

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1 another --
2 Q. Where do you draw that -- I'm sorry,
3 Doctor, to interrupt you.
4 But where do you draw that -- how -- how
5 did you come across that assumption? Where -- where
6 do you -- where do you draw that assumption from?
7 A. I think that would be -- I think I
8 discussed this in my -- my assignment and my
9 understanding of the complaint.
10 Q. Okay.
11 A. Let's see.
12 So in paragraph 8, it says, "The proposed
13 medical monitoring class consists of individuals
14 'who consumed a sufficiently high Lifetime
15 Cumulative Threshold of NDMA, NDEA, or other
16 nitrosamine, in generic valsartan-containing drugs
17 manufactured by or for Defendants."
18 So the -- the class are the individuals
19 who consumed this. It's not named that the
20 third-party payors are in that class. This is in
21 contrast to the other class of economic loss where
22 the third-party payors are included in that class.
23 And that's in paragraph 9.
24 Q. So that -- that is how you have reached
25 that conclusion, that is how you -- you have that

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1 assumption, right?
2 A. That's my understanding of the complaint.
3 Q. Did anybody provide that understanding to
4 you or did you just -- is that your understanding,
5 sitting here with your own interpretation?
6 A. That's my understanding after having read
7 the complaint and bringing this up with the
8 attorneys involved in the case.
9 Q. And if you read the beginning portion of
10 paragraph 8, "In regards to the proposed medical
11 monitoring class, I further understand that, among
12 the remedies requested, Plaintiffs seek" -- you
13 know, quote -- "seek injunctive and monetary
14 relief, including creation of a fund to finance
15 independent medical monitoring services."
16 Where do you -- or do you see within that
17 language any implication with respect to cost
18 sharing?
19 A. It just reads to -- it read to me that the
20 class for medical monitoring were patients, and
21 third-party payors were explicitly not included.
22 They were not named in that class. And that is
23 contrast with the second class of economic loss
24 where third party payors are explicitly named.
25 Q. So that's the basis for your -- for that

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1 assumption and that conclusion?
2 A. Correct.
3 Q. And you're not -- not a lawyer, right?
4 A. No.
5 Q. Okay. And this -- this -- this assumption
6 was also provided to you, or in part, by counsel; is
7 that correct?
8 A. That is --
9 MR. STOY: Objection. Asked -- hang on.
10 Objection. Asked and answered.
11 Objection. Form. To the extent it misstates what
12 he previously testified to.
13 THE WITNESS: Correct. I previously said
14 that I read the complaint.
15 MR. STOY: Go ahead.
16 THE WITNESS: This distinction, I noticed
17 this distinction in the complaint, and I
18 discussed -- I discussed this idea with the lawyers
19 involved in this case.
20 BY MR. MIGLIACCIO:
21 Q. I see.
22 And is it fair to say that if you -- how
23 many class action complaints have you read?
24 A. This is my first one.
25 Q. First one. Got it.

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1 Is it fair to say that if you -- if this
2 assumption was incorrect with respect to cost
3 sharing that it would alter your opinions in some
4 fashion?
5 MR. STOY: Object to the form.
6 THE WITNESS: I don't know if you want to
7 clarify what you mean by "alter in some fashion,"
8 but there are -- there's a section in my report on
9 cost sharing.
10 BY MR. MIGLIACCIO:
11 Q. Uh-huh.
12 A. And that is under the assumption that we
13 are interested in what patients are paying.
14 If we are not interested in what patients
15 are paying and there is some other concept that is
16 not well defined, it would need to be defined first,
17 and it would likely -- it's possible that could lead
18 to other variation that's unaccounted for.
19 Q. The question of variation of cost sharing,
20 if cost sharing wasn't an issue, there would be no
21 issue with respect to variation of cost sharing,
22 right?
23 MR. STOY: Object to form. Incomplete
24 hypothetical.
25 THE WITNESS: I guess what I'm saying is

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1 that we need to specify what is the object that we
2 are interested in quantifying. Even if there is no
3 cost sharing, there's a difference between charges
4 and difference between charges and costs and
5 ultimate amount that's reimbursed plus patient cost
6 sharing.
7 There's many different kind of optics that
8 we could be considering, and we would need to define
9 that first. And some objects will entail other
10 sources of variation.
11 BY MR. MIGLIACCIO:
12 Q. But cost sharing would no longer be a
13 source of variation if we're not talking about cost
14 sharing?
15 A. You're saying but cost sharing would no
16 longer be of interest if we're not talking about
17 cost sharing?
18 Q. No, would no longer be a source of
19 variation if -- if -- if it's not at issue in this
20 case?
21 MR. STOY: Objection. Incomplete
22 hypothetical.
23 Go ahead.
24 THE WITNESS: If the assumption is that
25 cost sharing is not at issue, then we would not

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1 consider variation in cost sharing.
2 BY MR. MIGLIACCIO:
3 Q. Got it.
4 Paragraph 117 in your report, you state
5 that -- let me know when you are there.
6 A. I'm here.
7 Q. Yep. 117.
8 A. Yep.
9 Q. Yep. Okay.
10 A. Yes.
11 Q. I'm looking for where I -- you state in
12 the middle, "Given the substantial price variation
13 that I summarize above, there is no reason to
14 believe that the average prices experienced by a
15 proposed" -- "proposed class members is the same as
16 the average prices experience" -- "experience by the
17 nation as a whole."
18 I think you just said that earlier.
19 A. Yeah.
20 Q. Isn't it fair to say that you have not
21 made an effort to determine the extent to which you
22 say the average prices experienced by proposed class
23 members is the same as the average prices
24 experienced by the nation as a whole? You haven't
25 tried to -- to determine that?

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1 A. In the report I do say how patients that
2 take valsartan are different than patients who don't
3 take valsartan. That is evidence in that direction.
4 But more broadly, in my report, I would
5 say that it would be infeasible to determine the
6 prices for patients in the class as -- for reasons I
7 just told you, including the unavailability of data.
8 Q. Well, if we take the cost sharing out,
9 which we'll -- we placed aside for these
10 discussions, what other data do you contend is -- is
11 unavailable?
12 A. Should we also define over what time span
13 this is going to be for?
14 Q. What -- what time span a medical
15 monitoring program will be for?
16 A. Right.
17 Q. Well, I think we can define it within a
18 finite period of time. We could say one year for --
19 for purposes of our discussion.
20 A. So you --
21 Q. I'm -- I'm just -- I'm giving you a
22 hypothetical to say could you determine that for --
23 for one year how much something would cost?
24 MR. STOY: So you're not -- you're not --
25 that's not a stipulation, huh, Nick?

<p style="text-align: right;">Page 178</p> <p>1 MR. MIGLIACCIO: No, that's a 2 hypothetical. To aid in the calculations here. 3 THE WITNESS: So we're not looking into 4 the future by very much. We're going to restrict 5 patients only to those who have Medicare. 6 BY MR. MIGLIACCIO: 7 Q. Uh-huh. 8 A. And we know exactly whether screening is 9 appropriate for every single patient individually, 10 then we could calculate the prices for patients in 11 Medicare for this year. 12 Q. Got it. 13 Have you made any effort -- you know, 14 since you -- you don't believe that the -- the 15 prices experienced by class members are the same as 16 the prices experienced nationwide, what efforts have 17 you made to determine how far off you believe them 18 to be? 19 A. I think this is supported by a few 20 analyses in the report. So it's supported by the 21 fact that patients who take valsartan are different 22 than patients who don't take valsartan. It's 23 supported by the variation in price among patients 24 seeing the same provider, MGH. 25 It's supported by also variation in price</p>	<p style="text-align: right;">Page 180</p> <p>1 class"? 2 A. So, for example, 5th percentile means 3 5 percent of the population is -- is, you know, at 4 the 5th percentile or below. Or 95th percentile is 5 5 percent of the population is at or above this 6 price. 7 So if you have a class that's 5 percent of 8 the population you could be as unlucky to get 9 something that's 400 percent off if you compare the 10 5th to the 95th percentile. 11 Q. When we're talking about the size of the 12 class, how do you mean in terms of a small class, a 13 big class, what do you mean by that? 14 A. So -- so kind of implicit in my previous 15 answer is you would ask how many people are in this 16 class and how many people are in the overall 17 population of the nation. That's one way of asking 18 that. 19 Or if you are -- even if under the 20 assumption that all members of the class -- you were 21 able to measure prices for some bigger sub -- bigger 22 set of people that include everybody in this set, 23 included people in the class, which I don't think is 24 true, you could use that bigger population. 25 So in our previous example where we're</p>
<p style="text-align: right;">Page 179</p> <p>1 that I -- that I show in other -- other exhibits 2 like figures -- Figure 9, "OptumHealth commercial 3 pricing," variation for the proposed procedures. 4 So if there's variation -- if there's no 5 variation then you would be much more confident that 6 the averages shouldn't differ between groups of 7 patients. But if there's a lot of variation, that 8 tells you that there's a lot of scope for averages 9 for one population differing from averages for 10 another population. And that, I think, is enough 11 evidence to show that you could be wildly off. 12 Q. When you say "wildly off," like, can you 13 ballpark that percentage? 14 A. Yeah, I mean, I think that's what some of 15 these figures do. You could be off by a factor of 16 like 400 percent if -- especially if the class is 17 not a big class. 18 If the class is a subset of patients who 19 took at-issue valsartan, it's a small population 20 relative to the entire population. And therefore, 21 you could be -- you could be in the 5th percentile 22 or in the 95th percentile and the difference between 23 the 5th and the 95th percentile for one given 24 provider is 400 percent. 25 Q. How do you define like a -- "not a big</p>	<p style="text-align: right;">Page 181</p> <p>1 only talking about the Medicare patients, we would 2 look at Medicare patients and we'd ask how big is 3 Medicare patients relative to the size of our class. 4 Q. And what are your -- do you have 5 assumptions with respect to the size of the class 6 here? 7 A. No. 8 Q. You have no assumptions? 9 A. No. 10 Q. Okay. 11 A. I mean, I -- I -- I have some intuition 12 that it's not going to be 50 percent of the U.S. 13 population. 14 Q. But no assumption on -- on -- on the size, 15 the number, the -- the -- you know, how many people 16 other than that intuition? 17 A. I haven't -- yeah, I haven't -- no. 18 Q. Have you asked for that information? 19 A. I so far have not asked for that 20 information, but I think that would be relevant for 21 moving forward. I wouldn't -- you know, I would 22 reserve the right to look at that in the future. 23 Q. Got it. 24 So for calculating the prices as we just 25 went through that hypothetical, in a limited</p>

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1 fashion, that we -- that we could calculate the
 2 prices for -- for patients in Medicare for a year,
 3 could you calculate that for two years?
 4 A. So I say in my report the farther into the
 5 future that you get, the more uncertain this is
 6 going to be.
 7 Q. Yeah.
 8 A. It's going to be more uncertain for
 9 private insurance than for Medicare, but even within
 10 Medicare, the Medicare budget changes every year,
 11 the conversion factor between RVUs and dollars could
 12 change and does change every year.
 13 The geographic price indices between
 14 different regions in the country, that changes. It
 15 could change quite drastically. For example, Alaska
 16 doubled in one year.
 17 So the farther that you move out, even
 18 within Medicare, there would be more uncertainty on
 19 prices alone.
 20 But I think the bigger point, this might
 21 not be -- this is kind of a combination of both
 22 Kaplan and Song, is that we can't evaluate the
 23 overall spending for a medical monitoring program
 24 only by asking about prices. We have to ask what
 25 are the services that are going to be rendered and

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1 this -- there's a lot of uncertainty about what
 2 those services would be the farther we move out.
 3 Q. So how would -- you know, would it be
 4 possible to do two years if you knew what the
 5 services are or the menu of service?
 6 A. I said it's -- it's possible, but it
 7 becomes more uncertain.
 8 Q. Okay.
 9 A. Moving from one year to two years.
 10 Q. How about three years?
 11 A. More uncertain then.
 12 Q. Okay. So your work in the NBER, do you
 13 ever work on budgeting, working in the NBER?
 14 A. The government budget?
 15 Q. Or -- or have you ever dealt with
 16 budgeting issues working in that capacity, in -- in
 17 that --
 18 A. Can you clarify what you mean by
 19 "budgeting issues"?
 20 Q. Where the government, the federal
 21 government seeks to budget things out into the
 22 future, right, isn't that typically how the federal
 23 government works, they have a budget and it -- they
 24 have amounts that -- that are -- that are set into
 25 the future?

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1 MR. STOY: Object to the form.
 2 THE WITNESS: I'm familiar somewhat with
 3 how the budget for Medicare has been set.
 4 BY MR. MIGLIACCIO:
 5 Q. What -- what is your familiarity with
 6 that?
 7 A. So there is some budgeting into the future
 8 but this could be changed by Congress any given
 9 year.
 10 Q. Uh-huh. How -- tell me, how is it -- what
 11 is your familiarity of how -- how does Medicare get
 12 budgeted into the future?
 13 A. It's very complicated. I know that a lot
 14 of it has to do with politics. I know that one
 15 example of this is called a "doc fix" where in order
 16 to have a balanced budget there was some promise to
 17 eventually lower prices on medical spending for
 18 physician services but every year or every couple of
 19 years there'd be a delaying of this.
 20 So I think there is quite a bit of
 21 political influence on what the Medicare budget is.
 22 It's not some formula that gets set by something
 23 that's free of politics and is kind of -- you know,
 24 is -- is let to run in some predetermined fashion.
 25 Q. How far out does the Medicare budget get

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1 set; do you know?
 2 A. I think in -- as I said, in practice, it
 3 could change in a year.
 4 Q. Uh-huh.
 5 A. So by definition it's not in practice set
 6 in stone.
 7 Q. And is it determined annually, on an
 8 annual basis?
 9 A. I think it could change at any point.
 10 Q. The government knows how much it spends on
 11 Medicare for a given year, right?
 12 MR. STOY: Objection. Asked and answered.
 13 THE WITNESS: For -- for a given year, I
 14 believe the government could track down how much it
 15 spent on Medicare.
 16 BY MR. MIGLIACCIO:
 17 Q. Do you believe -- you know, is it your
 18 opinion that for one price to be representative of
 19 another, they would need to be the same?
 20 A. Say that again.
 21 Q. Is it your opinion that for one price to
 22 be representative of another, they would need to be
 23 the same?
 24 A. For one price to be representative of
 25 another price, the two prices would have to be the

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1 same?

2 Q. Yes. That -- that's what I'm asking you.

3 A. I'm not sure what I -- I'm not -- I'm not

4 sure I understand that question. Sorry.

5 Q. So if you were to -- if you were to

6 attempt to estimate the prices for a -- a patient

7 population, would you -- you would look at

8 representative prices, right; is that something that

9 you would do?

10 MR. STOY: Objection. Incomplete

11 hypothetical.

12 THE WITNESS: What do you mean by

13 "representative prices"?

14 BY MR. MIGLIACCIO:

15 Q. You would look at average prices?

16 A. Average prices. I'm not sure -- yeah, I'm

17 not sure I understand, like -- ultimately, what we

18 want to do is to be able to quantify total spending.

19 I'm not sure what we mean by "average prices."

20 Like, is there some weighting to the

21 prices? The average prices alone don't -- some

22 unweighted version of average prices is not going to

23 tell you how much we are going to spend in a medical

24 monitoring program.

25 Q. I'm going to direct you to paragraph 117.

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1 You can tell me when you are there.

2 A. Yes.

3 Q. Yeah. I mean, you discuss Dr. Song's

4 proposed estimates.

5 A. Uh-huh.

6 Q. Based on national averages and -- and you

7 say, "not average prices specific to members of the

8 proposed class."

9 A. Uh-huh.

10 Q. And you say, "Given the substantial price

11 variation that I summarize above, there is no reason

12 to believe that the average price" -- "prices

13 experienced by proposed class members is the same as

14 the average prices experience by the nation as a

15 whole."

16 A. Uh-huh.

17 Q. So my question to you is, that given that

18 you don't believe the prices experienced by class

19 members are the same as the prices --

20 A. Uh-huh.

21 Q. -- experienced nationwide, what efforts

22 have you made to determine how far off they are,

23 like how far off do they vary?

24 A. I think as I said before, the analyses

25 that show that the class members -- or people that

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1 take valsartan are different than people who don't

2 take valsartan and that prices vary in several of

3 the analyses that I do within Optum or within MGH

4 suggests that they could vary quite a bit.

5 Q. They could. But -- but have you

6 determined that they do?

7 A. I think my level of certainty is quite

8 high that they do vary. I haven't seen any evidence

9 to suggest that they would be the same.

10 Q. So how much do they vary?

11 A. In order to -- in order to do this you

12 would have to first specify the class, right?

13 Q. Right. And the class has not yet been

14 determined.

15 A. Right.

16 Q. Class hasn't been certified. So have

17 you --

18 A. But I can tell you that --

19 MR. STOY: Hang on, Dr. Chan. I don't

20 think there was a question pending.

21 BY MR. MIGLIACCIO:

22 Q. So have you determined, then, how much

23 they vary here?

24 MR. STOY: Objection. Asked and answered.

25 THE WITNESS: If there's no class, then I

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1 wouldn't be able to -- and I think this is part of

2 the problem of -- of defining a class. First you

3 would need to know who -- you would need to define

4 the class in order to ask whether it's feasible

5 to -- the class would of course have to be captured

6 by either a -- fully captured by Medicare data or

7 fully captured by sources of data that are publicly

8 available in order for you to ask how would the

9 prices differ for members of the class versus

10 other -- other patients.

11 What we can do is that we know that

12 patients who take valsartan are different than

13 patients who don't take valsartan. That's a

14 starting point. That would suggest that these

15 patients are -- there's no reason why you would

16 think that -- so patients who take valsartan have,

17 you know, hypertension. They have heart failure.

18 And those by construction, like the fact

19 that they take valsartan implies certain medical

20 conditions that other patients don't have. You

21 would expect that patients that have certain medical

22 conditions to have different forms of insurance.

23 And if you have different forms of

24 insurance, you would expect that the prices should

25 be different for those patients than for patients

<p style="text-align: right;">Page 190</p> <p>1 who don't take valsartan. 2 BY MR. MIGLIACCIO: 3 Q. If we disregard the cost sharing, right, 4 that -- that -- that different forms of insurance 5 issue falls away, right? 6 A. No. If you are saying, you know, some 7 patients might be more likely to be covered under 8 the VA or some patients might be more likely to have 9 private insurance, again it all depends on what 10 object you really want to focus on. 11 Even if you disregard cost sharing and you 12 say it's the object of how much the insurance 13 company pays providers, which I'm not sure is 14 what -- it hasn't been specified exactly what the 15 object should be, but if that is the object, that 16 would depend on whether the patient has private 17 insurance or Medicare or is a patient at the VA. 18 Q. But, again -- and -- and I -- I mean, I 19 think you've answered this, but I want to make sure 20 that I understand it. 21 You have not made any effort to determine 22 whether prices experienced -- whether the prices for 23 class members would vary by a certain percentage 24 from the national average prices? 25 A. I just don't have the --</p>	<p style="text-align: right;">Page 192</p> <p>1 think there's -- I mean, you point to them. Do you 2 think there's some -- are -- are they useful for -- 3 for your -- for your opinion? 4 A. I don't think they would -- they're enough 5 for us to estimate how much paying for medical 6 monitoring would be for this class. 7 Q. But you used them to argue that -- or to 8 opine, rather, that -- that it -- that it can't be 9 estimated; is that right? 10 A. In some of the stuff that you've read from 11 my report, I say that the national average price is 12 different from -- for the -- different than the 13 price that would be applicable for members of the 14 class. 15 Q. And -- and you -- you don't have that 16 delta, you don't have that difference? 17 A. I don't think anybody has that. And I 18 don't think it would be feasible to calculate it 19 because you can't calculate the price. 20 Q. Is it fair to say that you can get much 21 more locally accurate commercial-to-Medicare price 22 ratios by using data that show local variations in 23 these ratios? 24 MR. STOY: Object to form. 25 THE WITNESS: Can you restate that</p>
<p style="text-align: right;">Page 191</p> <p>1 MR. STOY: Objection. 2 Hang on. 3 Objection. Asked and answered. 4 Go ahead. 5 THE WITNESS: I don't have the data to do 6 that. You can -- you can demonstrate that patients 7 who take valsartan are different than patients who 8 don't, but I don't have all of their private 9 insurance prices that they are facing, like -- and I 10 don't think anybody has those data. 11 BY MR. MIGLIACCIO: 12 Q. So -- so you -- you don't have an answer, 13 then. You don't -- you -- you have not reached 14 the -- 15 A. Yeah. And I think it's an opinion that 16 it's not really answerable unless you have much more 17 detailed data sources than are publicly available. 18 Q. Would you agree that Medicare prices are 19 available by geography at the state and local level? 20 A. Medicare prices are available, yes, 21 Medicare prices are available if you know the 22 provider type and if you know the geography and if 23 you know the service. 24 Q. Do you -- do you think that the national 25 average prices are useful in your analysis? Do you</p>	<p style="text-align: right;">Page 193</p> <p>1 question? 2 BY MR. MIGLIACCIO: 3 Q. Yeah. 4 Can you get much more locally accurate 5 commercial-to-Medicare price ratios by using data 6 that shows local variations in these ratios? 7 MR. STOY: Object to form. 8 THE WITNESS: I think my point is that you 9 actually don't observe the real ratios for many -- 10 for -- in many settings and for many providers, for 11 many insurers. 12 We have, like, limited -- we have limited 13 data. For example, Optum is from a specific class 14 of insurers. We have hospital prices for certain 15 insurers. But we don't have the data relevant that 16 we would need for the prices of this medical class. 17 So we wouldn't be able to calculate the ratios. 18 BY MR. MIGLIACCIO: 19 Q. This is a general question as to whether 20 you can get more locally accurate 21 commercial-to-Medicare price ratios by using data 22 that shows local variation in these ratios? 23 A. Do the data exist? Is it available? 24 Q. Would you agree to that, yes? 25 A. I don't think the data are available.</p>

<p>Page 194</p> <p>1 Q. You don't think -- you don't think that 2 there is data that allows you to get much more 3 locally accurate commercial-to-Medicare price 4 ratios, you don't think it exists? 5 A. I think we could get data that are more 6 locally accurate than the data that Dr. Song relies 7 upon. But I don't think we have data available to 8 get us what would be the relevant spending for a 9 medical monitoring program for this class that has 10 not yet been specified. 11 Q. Tell me about the more accurate local 12 data. Where does that data exist? Where can you 13 get it? 14 A. That is quite hypothetical. 15 I -- you know, I think -- what Dr. Song 16 relies upon is -- or at least in his report, is a -- 17 to my understanding, it's a paper that measures 18 private insurance prices for some population of 19 patients that's aggregated and compares that with 20 Medicare prices. So certainly you could do better 21 than that. 22 There are data on private insurance prices 23 that are incomplete. So, you know, they're 24 incomplete. They -- they -- they leave out 25 populations of patients. They're only in certain</p> <p>Page 195</p> <p>1 settings. 2 They may or may not have geographic 3 identifiers. And if you have geographic 4 identifiers, then you could come up with something 5 that is more, in your words, local to a geography. 6 But geography is not the only variation that we need 7 to account for. 8 Q. When you say certainly you can do better 9 than that, what -- in your last answer, what do you 10 mean by that and how much better could you do? 11 A. What I mean is that in Dr. Song's 12 methodology he's using a ratio from a paper that is 13 not published for this purpose. It's some average 14 ratio in some population of patients that is almost 15 certainly different than the population of patients 16 that we care about in this class. And it's a single 17 ratio. 18 And if you wanted to get more granular, 19 you could look at different locations, if there are 20 geographic identifiers. And that's what I mean by 21 you could do better. If you wanted to have 22 something that accounted for geographic variation in 23 the ratios, you could use local prices from -- and 24 private insurance, but those prices would omit, you 25 know, classes of patients that I just mentioned and</p>	<p>Page 196</p> <p>1 so they wouldn't -- there would be shortcomings 2 there. 3 So -- so there -- there are different 4 dimensions in which prices vary. Geography is one 5 of them. And there are others that you might 6 actually be worse. If you're focusing on, say, 7 Optum data, Optum data are only from a certain class 8 of private insurers. So you might do worse if you 9 focus only on Optum data. 10 Q. What would those shortcomings be? Could 11 you quantify how big they would be? How big -- how 12 big would we be from the truth? Like, how far off? 13 A. I can tell you that there's big variation. 14 If there's big variation that the potential 15 shortcomings could be as large as the variation. 16 Q. Do you know how -- have you quantified how 17 large the variation could be? 18 A. It's possible that the variation could be 19 as large as 400 percent. 20 Q. What is the basis for that opinion? 21 A. The basis of that opinion is that there's 22 variation between the 5th and the 95th percentile in 23 prices that is as large as 400 percent and if you 24 have a class that is the size that's small enough, 25 say, 5 percent of the population, then you could</p> <p>Page 197</p> <p>1 have very unfortunate variation where it's -- you 2 get your 400 percent off. 3 Q. Isn't it fair to say that most people 4 reside in the center of the histogram and not at the 5 tail ends, at the 5 percent or the 95th percentile? 6 A. It depends on the population. 7 MR. STOY: I was going to object to the 8 form. 9 THE WITNESS: It depends on the 10 population. If you say do most doctors reside in 11 the center of the overall U.S. population in terms 12 of income, the answer would be no. Most doctors 13 reside in the top 5 percent. 14 BY MR. MIGLIACCIO: 15 Q. Right. And I'm not asking about income 16 but I -- you know, I appreciate that. 17 I'm asking about, you know, healthcare 18 spending or healthcare prices that people -- that 19 would be paid for a person. 20 A. I think healthcare spending exhibits some 21 of the same properties as income. So there are big 22 kind of skewed -- they're -- they are not normally 23 distributed actually, the healthcare spending. 24 They're obviously all positives so they're not 25 normally distributed. They could be log-normally</p>
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<p style="text-align: right;">Page 198</p> <p>1 distributed. So there is a possibility that you 2 have skewed distributions and you could have 3 outliers. 4 This is well known, that certain regions 5 in the U.S. spend way more than others. There 6 are -- there are -- for example, McAllen, Texas, 7 versus San Antonio, Texas. So there could be -- you 8 could actually have a small population that is in 9 the tails of the distribution. The tails can be 10 quite large. 11 Q. Do you have any reason to believe that 12 people who ingested contaminated valsartan are not 13 in the middle of the population? 14 A. I don't have any reason to believe that 15 they are in the middle of the population because by 16 definition they have -- you know, first of all, we 17 would have to look at where -- who's in the class. 18 I mean -- so if you just say people who 19 take valsartan versus people who don't take 20 valsartan, that's a little bit easier and then you 21 could say are they similar to the average 22 population. I think probably not. They have heart 23 failure. They have hypertension. 24 Are they similar to some population maybe, 25 like you would have to work on specifying that</p>	<p style="text-align: right;">Page 200</p> <p>1 center of the histogram chart -- 2 A. It depends on -- 3 Q. -- even though -- 4 A. It depends on the population you're 5 talking about. If you're comparing two populations, 6 there's no guarantee that the most -- by -- it 7 depends on the distribution. It depends on whether 8 you're talking about one or two populations. In 9 this case, we're talking about two populations. 10 So you're asking whether most people in 11 one population falls in the center of another 12 population. There's no reason to believe that. 13 Q. But there's also no reason to believe they 14 reside in the tail ends, right? 15 A. I think there's something that 16 distinguishes the population that takes valsartan. 17 They have heart failure. They have hypertension. 18 There is something that distinguishes them. And 19 I -- I don't know if most of the population has 20 heart failure. Probably most of the population 21 doesn't have heart failure. 22 Q. Does not. So you're saying -- 23 A. Does not. 24 Q. -- you have -- you don't think -- but do 25 you -- do you think the majority of the population</p>
<p style="text-align: right;">Page 199</p> <p>1 population, but it's not clear to me how you would 2 specify that population that they're similar to. 3 Q. And -- but you have not done this analysis 4 to determine where a population of people who 5 consumed valsartan-containing drugs, contaminated 6 valsartan, where they would fall, right? 7 A. Again, I'm not sure if it's feasible to do 8 this analysis if you want to account for private 9 insurance prices and so forth. 10 Q. But to answer my question, you haven't 11 done it? 12 A. I have done an analysis to show how 13 patients who take valsartan are different than 14 patients who don't take valsartan. 15 I haven't done an analysis to show what 16 would the average price be for patients who take 17 valsartan compared to patients who don't take 18 valsartan, but I don't think an analysis could be 19 done if you want to account for private insurance 20 prices. 21 Q. Fair to say that you would have a reason 22 to assume that a -- that -- that our proposed class 23 would be in the middle because that's where most 24 people are, right? Most people -- isn't that -- 25 isn't there the -- most people do just fall into the</p>	<p style="text-align: right;">Page 201</p> <p>1 that takes valsartan has heart failure? 2 A. I would need to look further into that. 3 Q. You're not offering that opinion here? 4 A. I'm not offering that opinion. I'm just 5 offering the opinion that there are obvious 6 differences between people that take valsartan and 7 people who don't. 8 Some of this is in my report that 9 describes the characteristics of people who take 10 valsartan versus people who don't take valsartan. 11 Q. How would heart failure impact Medicare 12 costs for -- for the screening services that 13 Dr. Kaplan has detailed in his report? 14 A. Right. So as I mentioned in my report, 15 heart failure or just medical comorbidities would 16 impact whether somebody is a candidate for screening 17 or whether somebody has preferences that would make 18 screening make sense. 19 Heart failure is a disease for whom most 20 adults have a relatively limited life expectancy if 21 they have it. And given that, that would impact the 22 decision for whether somebody should be screened for 23 cancer. 24 Q. So it would impact -- and your opinion is 25 it impacts the decision of whether screening would</p>

<p style="text-align: right;">Page 202</p> <p>1 need to be done, but it doesn't impact the price, 2 the cost for a fixed service, right? 3 A. Oh, I see. For your -- your price -- 4 Q. Yeah. 5 A. Your question's about price? 6 Q. Correct. 7 A. If you have heart failure, that could 8 certainly -- and you don't have Medicare, that could 9 certainly impact the type of insurance that you 10 have. If you're a sick patient with heart failure 11 versus a healthy patient without heart failure, and 12 you're choosing between private insurance plans, you 13 would pick a different insurance plan if you have 14 heart failure, likely. 15 Q. Assuming the person is on Medicare? 16 A. Assuming the person is not on Medicare. 17 Q. That's your assumption, the person is not 18 on Medicare? 19 A. Correct. 20 Q. Got it. 21 But I mean, as we looked at, the average 22 age for a valsartan -- somebody who takes valsartan 23 was 63, right, that was with that -- that 63.3, and 24 the age of Medicare is 65, right? 25 A. Right. The -- the age --</p>	<p style="text-align: right;">Page 204</p> <p>1 interrupt you. 2 A. I think what I was saying earlier is that 3 patients may choose different insurance plans and 4 different insurance plans may have different prices. 5 Q. And you -- have you done that analysis 6 here to determine what that -- what that 7 differential might be? 8 A. For MGH in particular, I show that the 9 differential could be quite a bit. 10 Q. Have you done it for any other hospital 11 system? 12 A. No, but I think MGH is quite illustrative. 13 Q. I want to show you some of your -- I think 14 some of your papers. 15 MR. STOY: Hey, Nick, would this -- 16 MR. MIGLIACCIO: Yeah. 17 MR. STOY: Would this be a good time to 18 take ten? 19 MR. MIGLIACCIO: Sure. Yeah, we can do 20 that. 21 THE VIDEOGRAPHER: Okay. We're off the 22 record. The time is 1:41 p.m. Pacific time. 23 (Whereupon, a brief recess was taken.) 24 THE VIDEOGRAPHER: We are back on the 25 record. The time is 1:57 p.m. Pacific time.</p>
<p style="text-align: right;">Page 203</p> <p>1 Q. Eligibility. 2 A. -- of Medicare eligibility is 65. If the 3 average age is -- again, I think you asked this 4 question before. 5 If I know the average age is 63, can I say 6 that the majority of patients on valsartan is on 7 Medicare? And I think I said that I wouldn't be 8 able to automatically reach that conclusion. It 9 could be -- because you would need to know the 10 entire distribution. 11 Like, for example, if the distribution is 12 a normal distribution, and half the people are above 13 63 and half the people are below 63, you could have 14 close to half of the people not being on Medicare. 15 It all depends on the shape of the distribution, not 16 just the average of the distribution. 17 Q. If -- if you take away the cost sharing 18 issue that we talked about at some length, right, 19 the fact that somebody may have heart failure or a 20 comorbidity shouldn't impact the cost for a fixed 21 service, right? 22 MR. STOY: Object to the form. 23 THE WITNESS: For -- I -- 24 BY MR. MIGLIACCIO: 25 Q. For a screening service. I'm sorry to</p>	<p style="text-align: right;">Page 205</p> <p>1 BY MR. MIGLIACCIO: 2 Q. All right. Dr. Chan, I want to ask you a 3 few questions about some of your own academic 4 publications. And I'm going to move into the 5 exhibit -- the file of paper that you have submitted 6 to the New England Journal of Medicine. 7 Here we go. I can do it. All right. I 8 thought I got -- was getting the hang of this. 9 Okay. 10 MR. MIGLIACCIO: It will be Exhibit 5. 11 (Whereupon, Chan Exhibit 5 was marked for 12 identification.) 13 MR. MIGLIACCIO: And it is a New England 14 Journal of Medicine document. 15 Q. Let me know when you have a chance to see 16 it. 17 A. It's open. 18 Q. Okay. Great. 19 So is it -- is it fair to say that you 20 have asserted in your own work the importance of a 21 common methodology when it comes to the pricing of 22 medical services? 23 MR. STOY: Object to the form. 24 THE WITNESS: Is there a -- a part of this 25 article you'd like to draw my attention to?</p>

<p style="text-align: right;">Page 206</p> <p>1 BY MR. MIGLIACCIO:</p> <p>2 Q. I'm asking you generally. I mean, it's --</p> <p>3 it's a nine-page article. I'll ask you some</p> <p>4 specifics, but I -- that's a general question.</p> <p>5 A. Can you ask that again?</p> <p>6 Q. Sure.</p> <p>7 Is it fair to say that you have asserted</p> <p>8 in your own work the importance of a common</p> <p>9 methodology when it comes to the pricing of medical</p> <p>10 services?</p> <p>11 MR. STOY: Object to the form.</p> <p>12 THE WITNESS: I'm not sure. I...</p> <p>13 BY MR. MIGLIACCIO:</p> <p>14 Q. In this paper, you discuss using median --</p> <p>15 median time values in defining benchmarks versus</p> <p>16 mean values.</p> <p>17 Do you see that in the Discussion section?</p> <p>18 A. Uh-huh.</p> <p>19 Q. Then you go on to say that you use medians</p> <p>20 as an alternative, right?</p> <p>21 A. Uh-huh.</p> <p>22 Q. And you write "average" or "on average"</p> <p>23 roughly nine times in -- in this study, right?</p> <p>24 I mean, you can look for it.</p> <p>25 A. Right, yep, 9 percent. Is that right?</p>	<p style="text-align: right;">Page 208</p> <p>1 it a lot?</p> <p>2 A. I think this is similar to our previous</p> <p>3 discussion about the use of averages in research.</p> <p>4 It -- it's important to use the right averages.</p> <p>5 In this case, you know, this is not a</p> <p>6 paper just comparing one average with another</p> <p>7 average. It's a paper that is comparing the average</p> <p>8 for a given procedure in a survey with an average in</p> <p>9 a nationally representative data source that --</p> <p>10 or -- sorry.</p> <p>11 It's -- it's an average in a data source</p> <p>12 that measures the time of how long this surgery</p> <p>13 takes, called NSQIP, and we are asking whether these</p> <p>14 two averages match up. And this is actually a</p> <p>15 research finding. It's not -- it's not -- we're</p> <p>16 actually asking whether the two averages for a given</p> <p>17 procedure match up. It's not -- it's not</p> <p>18 predetermined that they would match up.</p> <p>19 So it's -- it's kind of like -- it's a --</p> <p>20 it's a -- it's a research inquiry to ask whether</p> <p>21 using this average is representative of another</p> <p>22 average. And in this case, these two measures do</p> <p>23 closely follow each other, but it's not a foregone</p> <p>24 conclusion that they would.</p> <p>25 Q. But it's fair to say that, you know,</p>
<p style="text-align: right;">Page 207</p> <p>1 Q. No. I said you used the word "average" --</p> <p>2 A. Oh.</p> <p>3 Q. -- throughout and -- throughout the --</p> <p>4 A. Oh, okay.</p> <p>5 Q. -- paper.</p> <p>6 A. Yeah. I think -- yeah, go ahead. Sorry.</p> <p>7 Q. Yeah. And I do see that you -- that --</p> <p>8 that 9 percent, is that the average that you --</p> <p>9 you've reached ultimately?</p> <p>10 A. No, actually, that paragraph is an example</p> <p>11 where...</p> <p>12 Q. I'm sorry, were you finishing --</p> <p>13 A. No, I'm -- I'm reading it.</p> <p>14 Q. Okay.</p> <p>15 A. Sorry.</p> <p>16 Q. Please, no, go ahead. I didn't mean to --</p> <p>17 don't mean to interrupt your reading.</p> <p>18 A. Yeah, I think that discussion is just</p> <p>19 saying that there are different ways of -- different</p> <p>20 moments in a distribution to consider. Mean is one,</p> <p>21 or average. And the other one is median. And they</p> <p>22 just tell you different things.</p> <p>23 Q. Would you say this emphasis of averaging,</p> <p>24 the importance of averaging across data points, is</p> <p>25 it -- is it important in your research? Do you do</p>	<p style="text-align: right;">Page 209</p> <p>1 whether -- whether it was right or wrong, right,</p> <p>2 whether -- whether the -- whether they matched or</p> <p>3 they didn't, it's a common methodology to average,</p> <p>4 right? You used a common methodology, a methodology</p> <p>5 of averaging to determine if they -- if they would</p> <p>6 match the national average, right?</p> <p>7 MR. STOY: Object to the form.</p> <p>8 THE WITNESS: I don't know what you mean</p> <p>9 by common method -- I mean, I don't...</p> <p>10 BY MR. MIGLIACCIO:</p> <p>11 Q. You used the methodology of averaging,</p> <p>12 right?</p> <p>13 A. Not really. I don't think that's what</p> <p>14 we're doing here.</p> <p>15 Q. I thought you just told me that you were</p> <p>16 determining -- you were looking at something</p> <p>17 national versus another dataset --</p> <p>18 A. Uh-huh.</p> <p>19 Q. -- and to see if -- if they matched on</p> <p>20 average?</p> <p>21 A. We were asking whether average times for a</p> <p>22 given procedure matched average survey responses.</p> <p>23 This is a research question. It's not a common</p> <p>24 methodology per se. I'm not sure what you mean by</p> <p>25 "common methodology."</p>

<p style="text-align: right;">Page 210</p> <p>1 Q. Well, you used -- I mean, you -- you did 2 these calculations to see if -- if -- if they would 3 match, right, that's what you did? 4 A. That's maybe in one exhibit in this -- 5 okay. There are several exhibits in this -- in this 6 paper. 7 Exhibit 1, Figure 1, asks whether -- this 8 is kind of -- it's kind of most directly related to 9 what you're saying, which is the -- whether the 10 average time that we observe in one dataset matches 11 the average survey in another -- a survey response 12 for the time in another dataset. 13 Now, Figure 2 is doing something very 14 different, which is asking about discrepancy. 15 That's, you know -- and discrepancy that kind of 16 changes over time. So that's not just comparing 17 averages. 18 Figure 3 is asking about the implications 19 of discrepancy on different surgical specialties 20 such as orthopedic surgery, urology, general 21 surgery, showing that these implications can be 22 large in terms of dollar terms. 23 For example, orthopedic surgery is paid 24 more than \$150 million more than what it would get 25 if they had resorted to another measure. And</p>	<p style="text-align: right;">Page 212</p> <p>1 for this one particular exercise. But as I said, we 2 also could do it in terms of medians instead of 3 averages. 4 Q. Uh-huh. 5 A. And in this exercise, it was a regression. 6 So after you have each individual observation, which 7 is a procedure, a surgical procedure is one 8 observation -- or a surgical procedure at a given 9 point in time is one observation. We have many 10 observations of these. Then we run a regression 11 that kind of fits a line on these points here. 12 Q. When you say you could also use the 13 median, what did you do with respect to the median? 14 A. So instead of using an average time from 15 the NSQIP data we could use the median time. That's 16 just a different moment in the distribution. 17 Q. Uh-huh. 18 A. And so when we do that, I mention 19 discussion that we get a different result if we use 20 the median instead of the average. 21 Q. Got it. 22 What was -- what's the difference? 23 A. It's a 9 percent difference in this case. 24 Q. Between the average and the median? 25 A. Uh-huh.</p>
<p style="text-align: right;">Page 211</p> <p>1 cardiothoracic surgery is paid about \$125 million 2 less than it would have been paid if it kind of used 3 another measure. 4 And then Figure 4 is asking whether 5 discrepancies are kind of resolved with 6 re-evaluation. So it's focusing on the 7 discrepancies. 8 So I don't think this paper, overall, is 9 only about comparing averages. It's about -- it's 10 much more. 11 Q. Got it. I understand. 12 So -- and I appreciate that clarification. 13 But for -- for Figure 1, who did the 14 averaging work? Was that something that you did or 15 your team did in -- in gathering -- in gathering the 16 dataset and averaging it? 17 A. I don't know if I would characterize 18 Figure 1 as like a dataset of just doing averaging 19 work. It's -- this work overall was done by me and 20 my research team. Some of them are coauthors on 21 this paper. Others are research assistants. 22 Q. What was -- what did you do beyond just 23 averaging it? 24 A. I would say that's just the first step. 25 We need a dataset with -- we chose these averages</p>	<p style="text-align: right;">Page 213</p> <p>1 Q. Got it. Okay. 2 Who did that work in determining the 3 median information, was that you or -- 4 A. The same research team. 5 Q. Got it. Got it. 6 And that's a methodology that you -- that 7 you use frequently determining medians? 8 A. Often. Oftentimes the median is a better 9 measure. If the distribution is skewed, you might 10 want to use the median instead of the average. 11 Q. Got it. 12 Are there other measures other than median 13 and average that you use -- 14 A. Yes. 15 Q. -- in analyzing datasets? 16 A. Quantiles, like I -- like I mentioned in 17 the -- like I use in the report, there's like 18 95th percentile, 5th percentile. There's a -- 19 they're -- those are called quantiles. 20 Q. Quantiles. 21 A. And sometimes you kind of work with logs, 22 like log -- logarithmic transformation. So you 23 might take a mean of the log instead of a -- just 24 the mean. So you first take a log, logarithm, of 25 the value, then you take the mean.</p>

<p>Page 214</p> <p>1 Q. And you use that methodology as well in 2 your work as an economist, as a healthcare 3 economist? 4 A. Yeah, I'm not sure if I'd call it a 5 methodology. They're just different kind of ways 6 to -- ways to characterize distributions. 7 Obviously, the most comprehensive way is 8 just to show the entire distribution but you might 9 focus on various moments of the distribution. You 10 can focus on quantiles and medians, on averages. 11 You might transform the distribution by first 12 applying a logarithm to it, then taking an average. 13 And that's quite different than just taking the 14 average of the underlying distribution. 15 So there are various kind of 16 transformations of the underlying data and there are 17 different ways to characterize a distribution. 18 Q. When you -- if you were to do that, 19 what -- what would -- what does it do to take the -- 20 I think you said take a -- first apply a logarithm 21 to it and then take an average? 22 A. Uh-huh. 23 Q. What -- what -- can you explain that a 24 little bit more? 25 A. Many distributions are skewed. For</p>	<p>Page 216</p> <p>1 reliable. 2 Q. Uh-huh. Got it. Got it. 3 Let me -- I want to show you something 4 else. Bear with me. Okay. 5 I just put in what we'll make as 6 Exhibit 6, which is your -- your national -- your 7 New England Journal of Medicine response letter. It 8 should be coming up right quickly. 9 (Whereupon, Chan Exhibit 6 was marked for 10 identification.) 11 THE WITNESS: Yes. 12 BY MR. MIGLIACCIO: 13 Q. Let me know if you have that. 14 A. I do. 15 Q. Okay. So this study received three formal 16 published critiques in the form of letters to the 17 editor, right? 18 A. Uh-huh. 19 Q. And you responded to those critiques, 20 correct? 21 A. Yes. 22 Q. Okay. And I think -- is it fair to say 23 you acknowledged some limitations of the study 24 including some special cases where your methodology 25 was less applicable --</p>
<p>Page 215</p> <p>1 example, income or spending, medical spending. So 2 it would be quite fragile if you were to actually 3 take an average of the underlying distribution of 4 spending and it would be much more robust if you 5 took a logarithm. 6 What a logarithm does is it transforms a 7 variable that ranges from just above zero to a very 8 large number, to something that's much more well 9 behaved and symmetric -- potentially around zero, so 10 it transform -- it might transform something to a 11 more normal distribution. 12 And that's kind of -- earlier in my 13 deposition I mentioned something called a log-normal 14 distribution. 15 Q. Uh-huh. 16 A. That is something that only starts looking 17 like a normal distribution when you take a 18 logarithm. 19 Q. Got it. 20 You used -- and used that methodology, 21 too, in -- in -- when you create averages? 22 A. Yeah, again, I'm not sure if I would call 23 it methodology. It's just a way of transforming -- 24 it's -- it's a very basic mathematical operation to 25 transform data into something that more -- is more</p>	<p>Page 217</p> <p>1 A. Uh-huh. 2 Q. -- but you went on to defend the study by 3 arguing that, and I quote, "Our study goal was to 4 identify and characterize forms of inaccuracy in the 5 RUC's time estimates and develop a general approach 6 for obtaining better estimates. The crux of that 7 approach is the use of large, longitudinal data 8 sources." 9 A. Uh-huh. 10 Q. And, "We welcome debate, reflection, and 11 refinements regarding the most appropriate data 12 sources and estimation techniques." 13 Did I read that correctly? 14 A. Yes. 15 Q. Is it fair to say that you were using 16 estimation techniques in your -- in -- in your 17 paper, in the underlying paper? 18 A. Estimation techniques. 19 I'm just going to read this again. 20 Q. Yeah, I want you to -- please take -- 21 A. Yeah. 22 Q. Feel free. 23 A. I believe this reply in the critiques are 24 almost entirely about multi-procedure -- cases where 25 more than one procedure is done at the same time; is</p>

<p style="text-align: right;">Page 218</p> <p>1 that right? That's my interpretation of -- upon 2 re-reading the reply. 3 Q. Is it fair to say that you used estimation 4 techniques? 5 MR. STOY: Object to the form. 6 THE WITNESS: I'm not sure what you mean 7 by "estimation techniques." 8 BY MR. MIGLIACCIO: 9 Q. So I'm just going to read the last 10 sentence of your reply, which is, "We welcome 11 debate, reflection, and refinements regarding the 12 most appropriate data sources and estimation 13 techniques." 14 Do you see that? 15 A. Uh-huh. 16 Q. What did you mean by that? 17 A. I think I meant -- so the entire goal of 18 this -- this committee called the RUC, the relative 19 value scale update committee, is to form estimates 20 of certain things that are going to go into the 21 decision-making process of how much to price a 22 procedure for Medicare. 23 So they have a technique, which is to, you 24 know, use surveys and ask physicians how long they 25 spend on a given procedure. That's their estimation</p>	<p style="text-align: right;">Page 220</p> <p>1 is about time. 2 Q. Uh-huh. Is it fair to say there's a -- 3 there's variation in time that surgical procedures 4 take across different people -- 5 A. Yes. 6 Q. -- of patient populations? 7 A. Yes. 8 Q. And what is the R -- the RUC? What -- 9 what is the -- what is RUC seeking to do? What is 10 the purpose of RUC? 11 A. The purpose of the RUC is to make 12 recommendations to how Medicare might price services 13 in the Medicare physician fee schedule. 14 Q. Got it. 15 So there may be variations across patients 16 for patient populations that are reflected in NSQIP. 17 RUC seeks to price those services regardless of the 18 variations; is that fair? 19 A. Sometimes, you know, it might change. 20 This is -- you know, it's a good question. Like 21 sometimes, because things vary so much, you might 22 decide to have two different services instead of one 23 service. 24 Q. Uh-huh. 25 A. So it's --</p>
<p style="text-align: right;">Page 219</p> <p>1 technique. And so this paper is about the accuracy 2 of their estimation technique and what's reflected 3 in another data source, in this case, the NSQIP. 4 So I'm not sure if I would say I use 5 estimation techniques or I'm commenting on how their 6 estimation technique compares with measures in 7 another data source. 8 Does that make sense? 9 Q. I -- I think so. 10 What -- what is the NSQIP? 11 A. This is the National Surgical Quality 12 Improvement Program data source that measures time 13 spent on various procedures. 14 Q. How does it do that? 15 A. That is a good question. I'm not 16 intimately knowledgeable about exactly all of the 17 mechanisms that are put in place. But it records 18 the time that a surgery -- a surgical procedure is 19 started and it records the time that the surgical 20 procedure is ended. 21 I would assume that this takes some type 22 of report by the surgeon in question to report the 23 starting and the ending time, and then once you have 24 those, you can -- you -- you measure the amount of 25 time a given procedure took. So here an estimation</p>	<p style="text-align: right;">Page 221</p> <p>1 Q. But the same service, the same service, 2 same price, right? 3 A. But you could -- so how you define 4 services is completely -- it's a -- it's not set in 5 stone. 6 For example, colonoscopy has multiple 7 services associated with that, right, it's 8 colonoscopy with clipping. Sometimes you could, 9 like, define a service based on the patient that's 10 getting the service. 11 So when you say one service and it's very 12 different and there's only one price, that's not 13 entirely accurate because medical societies, the 14 AMA, you know, when they figure out how to design 15 CPT codes, they could actually specify different 16 services if those -- if that single service is 17 different enough in different cases. 18 Q. But there are certain codes, right, so -- 19 so if you have -- and I understand that the service 20 could -- there might be different types of 21 colonoscopies. But let's talk about the one that -- 22 I think you said colonoscopy with clipping, right? 23 That's one code, right? 24 A. I -- I would have to review the codes. 25 There -- there might be multiple codes.</p>

<p style="text-align: right;">Page 222</p> <p>1 Q. Okay. Let's take -- let's hypothetically 2 take one, right, one code. If that code is being 3 priced, the RUC seeks to -- to -- to impose a price 4 on that code regardless of whether there might be 5 variation of the time spent providing the service in 6 that particular code; is that fair? 7 A. What I'm saying is that the American 8 Medical Association does not necessarily take that 9 as given. The American Medical Association, which 10 houses both the RUC and the CPT committee, can 11 recommend that we have two different CPT codes and 12 not one CPT code. 13 Q. Sure. But in each CPT code there is one 14 price being paid; is that right? 15 A. For a given CPT code in a given year and 16 given geography for a given type of provider, 17 Medicare pays one price. 18 Q. Got it. 19 Regardless of the variation of the patient 20 population that receives that service or regardless 21 of whether the service might take longer in one 22 individual patient versus another? 23 A. That I'm not a hundred percent sure. I 24 know that there's a lot more nuance than even I am 25 aware of.</p>	<p style="text-align: right;">Page 224</p> <p>1 looking at individual Medicare claims and asking to 2 what extent is the Medicare reimbursement fully 3 determined by the characteristics that I just told 4 you. 5 Q. Is there a central -- is data kept on 6 deviation from the schedule? Does that data exist? 7 A. For Medicare? Yes. 8 Q. Uh-huh. It does? 9 A. Yes. 10 Q. Okay. And that data would be the data 11 that we would look at to determine, you know, 12 whether and what percentage there -- there may be a 13 deviation from the schedule on the whole? 14 A. Right. For -- for Medicare? Yes. 15 Q. Got it. 16 So for the Medicare prices, then, that we 17 just talked about, taking aside the deviation that 18 we don't -- haven't characterized, those prices are 19 knowable, right, depending on the geography, the 20 services provider -- you listed a few different 21 items, but those prices are knowable, right? 22 MR. STOY: Object to the form. 23 THE WITNESS: Aside from the deviations, 24 yeah. For Medicare, yes. 25</p>
<p style="text-align: right;">Page 223</p> <p>1 For example, if Medicare is -- is paying a 2 teaching hospital or the hospital has like sicker 3 patients in a -- some type of disproportionate 4 service pool where the patients are underserved, 5 Medicare can still deviate from its fee schedule and 6 pay a higher price. They can pay different prices, 7 even if.. 8 So what I just told you is a very stylized 9 world where it's just the geography, the type of 10 provider, the year, and the service. But largely 11 that's true for Medicare, but even -- even then, 12 there's a lot -- there's more nuance than I think 13 somebody who is steeped in Medicare would be able to 14 tell you. 15 Q. When you say "largely that's true," you 16 know, what percentage -- you know, how true would 17 that be, you know, would you say 95 percent true, 18 99 percent true? Do you have an estimate? 19 A. I can't really give you a number right 20 now, no. 21 Q. Does such a number exist somewhere? 22 A. It should. It should exist somewhere. 23 You can -- go ahead. 24 Q. Sorry. 25 A. I think you could do the analysis by</p>	<p style="text-align: right;">Page 225</p> <p>1 BY MR. MIGLIACCIO: 2 Q. Got it. 3 Do you use Medicare data in your work? Is 4 that -- is that information that you -- you use a 5 lot in your academic work? 6 A. I use it to some extent. 7 Q. What extent do you use it? 8 A. It's hard for me to place a percentage on 9 it. I would say nontrivial extent, probably not the 10 majority of my work. 11 Q. What -- okay. 12 I'm going to show you another paper here. 13 Bear with me. 14 MR. MIGLIACCIO: I'm going to name this 15 Exhibit 7. 16 (Whereupon, Chan Exhibit 7 was marked for 17 identification.) 18 BY MR. MIGLIACCIO: 19 Q. And it is a paper that you published in -- 20 let's see. I'll tell you in a second. 21 That was published in -- can you see it 22 now -- Quarterly Journal of Economics? 23 A. Uh-huh. 24 Q. Okay. Great. 25 I'll give you a chance to look at that.</p>

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1 A. Yep.
2 Q. Okay.
3 A. Uh-huh.
4 Q. Okay. This study, you focused on health
5 insurance prices, right?
6 A. Study focuses on pricing recommendations
7 from the same company that I just described, the
8 RUC.
9 Q. Uh-huh.
10 A. And it looks at Medicare prices. It also
11 looks at private insurance prices.
12 Q. Got it.
13 You use the term "average" eight times in
14 this paper.
15 A. Uh-huh.
16 Q. Is that right?
17 A. I would need to check. I don't have
18 any --
19 Q. Yep.
20 A. -- reason to dispute it.
21 Q. Okay.
22 A. Actually, I think --
23 Q. More than that.
24 A. It says 17 times.
25 Q. Yeah, that's what I got, too. Glad I'm

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1 wearing my reading glasses. I can -- I can --
2 A. Yeah.
3 Q. I wasn't before.
4 A. I say "median" twice.
5 I see -- say "standard deviation"
6 probably -- it's tucked with standardized so --
7 let's see. There it is. I say "standard deviation"
8 five times.
9 I say "variants" once. "Covariants" once.
10 I say "variation" 32 times.
11 Q. I see the standardized, too. Let's --
12 let's look at that.
13 What did you do to standardize this in --
14 you said -- and I'm looking at Figure 3. I think.
15 A. Uh-huh. Figure 3?
16 Q. Yeah -- or actually, I'll look at where --
17 where you say on page -- I guess on page 1316.
18 A. Uh-huh.
19 Q. The bottom of the first paragraph,
20 "Finally, for interpretation, we standardize" -- and
21 I won't try to say that equation because I'll mess
22 it up -- "by subtracting the sample mean and
23 dividing by the sample standard deviation, and
24 denote this standardized measure."
25 What -- so tell us what you did with

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1 respect to standardizing.
2 A. The standard -- the term "standardize"
3 means to do exactly that, you subtract the mean and
4 you divide by the standard deviation. The mean is
5 the first moment and the standard deviation's the
6 second. It's the square root of the second moment.
7 And the second moment is a measure of variation.
8 Q. I see.
9 So what -- what is the -- you were a math
10 major, right, I think I saw that in your resumé.
11 A. Yes.
12 Q. I could see how that would come in handy
13 once you move into economics.
14 What is the benefit of standardizing the
15 dataset that you -- that you standardized here? Why
16 did you do it?
17 A. The primary benefit is that you can
18 then -- you become -- you make the scale of the
19 variation the same between two different variables.
20 So you're standardizing -- if you divide it by the
21 standard deviation, it means that you're not going
22 to have one data -- one set of observations that --
23 values that range from, say, zero to, like, 8,000
24 and another one that ranges from, like, 0.5 to 3.5.
25 Like it's -- when you standardize

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1 something, you make the distributions comparable by
2 having standard deviation by definition being zero.
3 If you divide by the standard deviation, the
4 distribution of the standardized variable is going
5 to have a standard deviation of one and a mean of
6 zero. So you don't have to worry about what's
7 called the location of the variable, which is the
8 mean, and the variants of the variable because it's
9 all standardized to zero and 1.
10 Q. Got it.
11 What was the dataset here that you were
12 working with?
13 A. This one -- the thing that I'm
14 standardizing is quite an involved variable, which
15 is -- it's described in equation 4 there -- where
16 it's quite involved.
17 What I would need to know to do that, to
18 calculate that, is this -- first you would need to
19 know this little A -- okay. So in order to -- to
20 know this you'd have to go to equation 3, which
21 tells you what this little A thing is.
22 This little A thing is -- okay. And we're
23 actually having to go to equation 2. I think.
24 Q. Yeah, yeah, yeah. And I have to go back
25 to -- yeah, yeah. Okay.

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1 A. Okay. So I don't want to waste your time
 2 here because it's going to be quite involved and I'm
 3 not sure it's related to --
 4 Q. Yeah, yeah, let me -- let me try to -- let
 5 me try to reframe my question.
 6 When -- the dataset that you were working
 7 with -- I think you say you -- you had three
 8 datasets; is that right? I'm -- I'm just trying to
 9 see what -- what was the -- what were the datasets
 10 that you were working with in this paper?
 11 A. Uh-huh. Umm, I believe that it might be
 12 in -- is that in the paper described? There's a
 13 Section III.A on page 1310 that talks about the data
 14 that I'm using.
 15 Q. Yep. Yep. Three sources of data.
 16 A. Yeah.
 17 Q. RUC's liberations. Yep.
 18 A. Yep. So there -- there's -- roughly
 19 speaking, I know each proposal -- this is about the
 20 pricing decisions that the RUC makes, or the pricing
 21 recommendations.
 22 And so for each CPT code that gets priced,
 23 I know who are the people that are on the proposal,
 24 so it -- it's a political process in some ways where
 25 if there's a CPT code that is done by cardiologists

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1 that needs to be priced, there will be a proposal
 2 that's written by cardiologists and maybe having
 3 other subspecialties or specialties on that
 4 proposals.
 5 So I'll know who are -- what are the
 6 identity of the specialties on that proposal, what
 7 are the identities of the specialties on this
 8 committee called the RUC. That's one dataset.
 9 The other dataset is using Medicare
 10 claims.
 11 And I believe -- is there a third dataset
 12 that is kind of using private sector prices. So
 13 that's not quite used in the equation that you
 14 highlighted. The equation that you highlighted uses
 15 the first two datasets.
 16 Q. Got it.
 17 But it sounds like -- I mean, you -- you
 18 have created some averages. You've used some
 19 standard -- you've standardized certain datasets.
 20 What other -- what other techniques did
 21 you use with this data?
 22 A. Yeah, I mean, so there are several, right.
 23 There's --
 24 Q. Yeah.
 25 A. If you look at equation 2, it's -- it's

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1 creating a share. It's -- it's summing up a number
 2 of quantities and dividing -- so there's a numerator
 3 which is part of the denominator so this is creating
 4 a fraction. And when you have the fractions, I'm
 5 creating a vector of fractions that's sum for one.
 6 That's equation 3.
 7 I'm calculating the Euclidean distance,
 8 which is the -- kind of the sum of squares and you
 9 take the square root of that and then once you have
 10 that, then I'm taking the maximum operator in
 11 equation 4 and then I'm taking an average of that.
 12 So an average does play a role in this but
 13 it's not the only operation that I'm doing here.
 14 Q. Right. Right.
 15 I mean, would you agree with me that --
 16 that you do use averages to arrive at a measure of
 17 central tendency in -- in your -- in your work?
 18 MR. STOY: Object to the form.
 19 THE WITNESS: Averages have a role here.
 20 But as I said earlier in the deposition, it really
 21 matters that you get the sample right. If you take
 22 an average of a different sample and try to apply
 23 that to another sample, that would be invalid.
 24 What I'm doing here is I'm describing --
 25 I'm not trying to say that this is a representative

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1 of some other sample that is not the same. I'm just
 2 describing the sample that I have. It's just a
 3 descriptive thing. I'm not saying that this should
 4 apply for something out of sample. This is just a
 5 description of the sample that I'm talking about.
 6 BY MR. MIGLIACCIO:
 7 Q. Is it fair to say that the use of averages
 8 to make sense of real world data and formulate
 9 useful parameters for policy decisions is a central
 10 tool of healthcare economics research?
 11 MR. STOY: Object to the form.
 12 THE WITNESS: Averages are useful but if
 13 you don't use them correctly, you could reach very
 14 misleading conclusions.
 15 BY MR. MIGLIACCIO:
 16 Q. So in this case, in this study, by
 17 definition, taking averages across datasets sets,
 18 they don't represent all data points exactly, right?
 19 An average doesn't represent every single data point
 20 exactly, it's an average; is that correct?
 21 A. By definition when you're calculating
 22 average you're losing information, yes.
 23 Q. That -- and that's the whole point of
 24 using an average, right?
 25 A. The point of using an average is most

<p style="text-align: right;">Page 234</p> <p>1 often to describe the dataset that you have -- to 2 describe the data that you have at hand. It becomes 3 dangerous when you use that to extrapolate to 4 another dataset that you don't have or to use -- to 5 extrapolate to another thing that you're interested 6 in that is different. That's kind of the point that 7 I'm trying to make. 8 Q. So I'm going to show you one more, one 9 more paper here. Let's see. This paper here -- 10 A. Oh. Let me just -- oh. 11 Q. Yeah, no, I'm -- I'm still -- I'm going to 12 ask you just a few more questions about this one. 13 A. Oh, okay. This is Exhibit 1 or Exhibit 7? 14 Q. This is still -- this is the same exhibit 15 we were just looking at, so -- 16 A. I just left it. Okay. So it's Exhibit 7. 17 Q. Exhibit 7, yes. Yep, yep, yep. Yep. 18 So this paper, is it -- 19 (Whereupon, a brief discussion off the 20 record.) 21 BY MR. MIGLIACCIO: 22 Q. Is it fair to say that this paper is 23 concordant with lots of other studies showing a 24 strong relationship between Medicare and commercial 25 prices?</p>	<p style="text-align: right;">Page 236</p> <p>1 the proposing specialty have higher affiliation 2 versus lower affiliation, you can see a big 3 difference in the slope here. Which means that the 4 relationship depends on that. 5 Second, is that I think for the purpose of 6 this case, we care not about kind of changes on 7 changes or the slope. We care about the levels. We 8 care about if private insurance is, say, 50 percent 9 higher or 20 percent higher or, you know, 10 percent 10 higher than -- than Medicare. So it's the exact 11 magnitude. 12 So even if we had something that was 13 exactly concordant, meaning if we increased the 14 price in Medicare by 5 percent, the private 15 insurance price would be increased by 5 percent. 16 The level matters a lot when we're coming 17 up with the price of the medical monitoring program 18 or the spending that would be involved in the 19 medical monitoring program because it could be 20 50 percent higher or it could be 20 percent higher 21 uniformly and that could be a big difference in how 22 much we decide to -- you know, how much we're saying 23 that the medical monitoring program has to -- is 24 going to cost. 25 So if you look at this graph on panel A,</p>
<p style="text-align: right;">Page 235</p> <p>1 MR. STROY: Object to the form. 2 MR. KUM: Madam Court Reporter, can you 3 read the question back to me. 4 (Whereupon, the reporter read the record 5 as follows: 6 "Question: Is it fair to say that this 7 paper is concordant with lots of other studies 8 showing a strong relationship between Medicare and 9 commercial prices?") 10 MR. KUM: Thank you. 11 THE WITNESS: So I think we have to be 12 precise about the relationship here. The figure 13 that talks about this relationship is in -- is 14 Figure 7 on page 1338. 15 And what it shows there is that it shows 16 various kind of slopes here. Which means that, 17 generally speaking, when you have a procedure that 18 has a higher price in Medicare, you're going to have 19 a procedure that has a higher price in private 20 insurance, okay. 21 But you can see that this slope differs 22 between different types of procedures. That's kind 23 of the main point of this figure, is that when a 24 procedure is priced by the RUC versus not or when 25 the procedure is priced in a case where the RUC and</p>	<p style="text-align: right;">Page 237</p> <p>1 for example, the scale on the Y axis goes from zero 2 to negative 4 logs. Whereas the scale on the X axis 3 goes from negative 6 to zero. That's huge in terms 4 of log terms. 5 Usually, when you talk about -- it's hard 6 to kind of interpret exactly, but when something is 7 0.5 logs higher that means it's generally 50 percent 8 higher. So if -- if you just look at the scale, the 9 scale tells you the private insurance is much more 10 generous than Medicare. And it could vary by a lot. 11 BY MR. MIGLIACCIO: 12 Q. Is it fair to say that in many situations, 13 notably when the RUC (verbatim) update committee, 14 the RUC, changes Medicare prices there is a 15 consistent and strong relationship between Medicare 16 prices and commercial insurer prices? 17 A. I think it depends. 18 Q. What does it depend on? 19 A. In this figure, what I'm showing you is 20 that it depends on the -- whether it comes from the 21 RUC. There are many price changes that don't come 22 from the RUC. And whether the RUC prices comes 23 from, like, a proposal process where the proposers 24 are more affiliated or less affiliated to the RUC. 25 And that's just one dimension in which it depends.</p>

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1 Q. Would you say it's fair that this paper
2 supports the use of Medicare as a way to predict or
3 estimate commercial prices, which may be --
4 A. No.
5 Q. -- imperfect but does offer an important
6 methodology; in other words, if you know Medicare
7 prices, you could use the existing academic
8 literature to estimate where commercial prices might
9 fall?
10 A. I think it would be -- go ahead.
11 MR. STOY: Object. Object to the form of
12 the question.
13 Go ahead.
14 THE WITNESS: That's -- that's not -- it
15 would not be fair to say that.
16 BY MR. MIGLIACCIO:
17 Q. Why not?
18 A. It, again, depends on the purpose that
19 you're trying to use it for. If the purpose is to
20 estimate the spending that you would have for a
21 medical monitoring program you might be 50 percent
22 off or you might be a hundred percent off.
23 Q. I'm -- I'm not asking you about estimating
24 anything for a medical monitoring program. I'm
25 asking you -- this is an academic paper, right, this

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1 wasn't published for a particular purpose. I'm
2 asking if that's a fair reading of your conclusion.
3 A. Can you restate -- a fair reading --
4 again?
5 Q. Yeah.
6 Is it fair to say in many situations,
7 notably, when the RUC changes prices, there is a
8 consistent and strong relationship between Medicare
9 prices and commercial insurer prices?
10 A. It's fair to say that when the RUC changes
11 prices, you will see changes in the same direction
12 in private insurance in general. This is talking
13 about changes on changes, not levels of prices. For
14 the medical monitoring program you would need levels
15 of prices, not just changes.
16 Q. The RUC sets the prices, though, does it
17 not?
18 A. It recommends prices in some cases.
19 Q. Okay. In some cases.
20 Didn't -- we just talked about that in
21 relation to your last paper, didn't we?
22 A. Correct.
23 Q. That it recommends prices and -- but
24 for deviation at times, which we haven't quantified,
25 those are the prices that are paid, right?

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1 A. The RUC recommends prices, then the
2 federal government decides whether to implement the
3 RUC's recommendations.
4 Q. Okay. How often -- so the RUC -- the
5 federal government decides and then what happens
6 after -- if the federal government decides to
7 implement them, then what -- what happens next?
8 A. Then it goes into the Medicare Physician
9 Fee Schedule.
10 Q. Got it. Got it.
11 Is it fair to say that your findings here
12 in this paper -- and I'm not asking you about the
13 medical monitoring at issue in this case -- but just
14 generally, you know, if the findings here provide
15 another data point to support the known relationship
16 between Medicare and commercial prices?
17 MR. STOY: Objection. Form and scope.
18 THE WITNESS: Can you restate the question
19 again?
20 BY MR. MIGLIACCIO:
21 Q. Yeah.
22 Is it fair to say that your findings here
23 in this paper generally provide another data point
24 to support the known relationship between Medicare
25 and commercial prices?

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1 A. It's fair to say that this study supports
2 a relationship between Medicare and commercial
3 prices.
4 Q. Have other people recognized that
5 relationship?
6 A. Yes.
7 Q. Okay. Who -- who else has recognized that
8 relationship?
9 A. In the economic literature, I think the
10 paper that most people would cite to you is Clemens
11 and Gottlieb, which I believe I cite in this paper.
12 Q. Uh-huh. Tell me about that paper. Was
13 that peer-reviewed?
14 A. Yes.
15 Q. Was this -- was this paper peer-reviewed?
16 A. Yes.
17 Q. Is the Clemens and Gottlieb paper known to
18 be reliable?
19 A. You know, again, it depends on reliable
20 for what?
21 Q. For the conclusion that there is a
22 relationship, a known relationship between Medicare
23 and commercial prices?
24 A. Yes.
25 Q. Okay. And your paper here, is it reliable

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1 for that conclusion as well?

2 A. My paper here is kind of -- adds

3 additional interpretation to that relationship.

4 Q. And is it reliable for that additional

5 interpretation?

6 A. I believe so.

7 Q. Who is Michael J. Dickstein?

8 A. He is a professor at NYU.

9 Q. And you were coauthors on this paper?

10 A. Correct.

11 Q. Did you receive any comments on it or that

12 you responded to? Was there any further

13 correspondence with respect to it?

14 A. In the same way that the --

15 (Technical difficulties.)

16 (Whereupon a brief discussion off the

17 record.)

18 THE WITNESS: Okay. I asked, in the same

19 way that the New England Journal paper had

20 correspondence?

21 BY MR. MIGLIACCIO:

22 Q. Yeah.

23 A. No.

24 Q. Okay.

25 MR. MIGLIACCIO: Why don't we -- I don't

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1 know how long we've been going but why don't we take

2 a quick five-minute break and go off the record.

3 THE VIDEOGRAPHER: Okay. We're off the

4 record at 2:51 p.m. Pacific time.

5 (Whereupon, a brief recess was taken.)

6 THE VIDEOGRAPHER: We are back on the

7 record at 3:03 p.m. Pacific time.

8 BY MR. MIGLIACCIO:

9 Q. Okay. All right.

10 Dr. Chan, just a few more questions before

11 I pass it to my colleague. Really about the

12 creation of your report.

13 Did you personally write the whole report?

14 A. I'm not sure what you mean by "personally

15 write," but yes, I did. I -- I wrote the -- the

16 entire report is mine, and I wrote the report.

17 Q. And with respect to the individuals that

18 helped you, did you screen them or vet them in any

19 fashion before you used their work?

20 A. I have a working relationship with

21 Analysis Group, and I did get to work with the

22 people that I mentioned on the call to a pretty

23 close extent. And I was able to evaluate the

24 quality of their work throughout as I prepared this

25 report.

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1 Q. Did you ever meet with any of them?

2 A. And what do you mean by "meet"?

3 Q. Like in person. I assume the answer would

4 be no, but I'm just curious.

5 A. Yes, the answer is -- is no. It was all

6 remote, by Zoom, by telephone.

7 Q. Did you vet the data that -- that was

8 provided to you? How -- you know, how did you

9 determine that the data that was provided to you was

10 accurate?

11 A. I did take a look at the data. I took a

12 look at the code that was used to produce the -- so

13 the -- basically the analytical process, which is

14 the raw data, the code, and the outputs and whether

15 the -- the outputs were consistent with my clinical

16 expertise and my knowledge of health policy.

17 So I evaluated the entire analytical

18 process from being aware of how the raw data looked

19 like, being aware of the analyses that were used to

20 process the data, and the outputs.

21 Q. Did you -- have you been paid yet for --

22 for your time?

23 A. I'm not sure if I've been paid for the

24 invoice that I submitted in January -- or, sorry,

25 for December. That would be the only time that it

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1 would be paid because I have not submitted invoices

2 for January or February.

3 Q. All right. When you do get paid, do you

4 get paid your rate plus the attribution at the same

5 time?

6 A. It's not always the same time. I think

7 it's usually separate, if I -- if I remember

8 correctly.

9 Q. How's -- how is it separate?

10 A. I believe there are -- there's payment for

11 my time.

12 Q. Uh-huh.

13 A. As a deposit or a check. I think in this

14 case, it's a deposit. And there is a separate

15 payment for the attribution.

16 Q. Got it.

17 And -- but are those made like

18 contemporaneously, is I guess what I'm asking?

19 A. Not necessarily. I think usually not.

20 Q. How -- do you know when you would be paid

21 for the attribution?

22 A. Not really. It's kind of random. I don't

23 quite understand the -- when the payments get made.

24 Q. You get them at some point after you get

25 the -- your payments?

<p style="text-align: right;">Page 246</p> <p>1 A. Potentially. It's not always after. I 2 don't understand the timing. 3 Q. Got it. Okay. 4 MR. MIGLIACCIO: Well, look, I thank you, 5 you know, for your time, and I want to pass the 6 question -- questions over to Layne. 7 THE WITNESS: Thank you very much. Thank 8 you. 9 EXAMINATION 10 BY MS. HILTON: 11 Q. Good afternoon, Doctor. My name is Layne 12 Hilton and I am an attorney for the plaintiffs and 13 I'm going to be asking you about the portions of 14 your report that pertain to Dr. Conti's analysis. 15 Do you have an understanding of what the 16 term "medical benefit" means? 17 A. I have an understanding of what it means 18 to me. I'm not sure if it's a technical term, but 19 it -- to me it -- I do have an interpretation of 20 that term. 21 Q. If I were to use the term "medical 22 benefit" to describe the activities of a commercial 23 health insurance plan that pertain to things like 24 doctors' appointments and tests and other sorts 25 of -- you know, all of the things that you basically</p>	<p style="text-align: right;">Page 248</p> <p>1 you, without you having to specify which cases, if 2 in any of your previous expert testimony you 3 provided testimony about the pharmacy benefit. 4 A. Yes. 5 Q. And what aspects of the pharmacy benefit 6 have you previously testified about? 7 A. I'm not sure what I can disclose other 8 than that I have testified on the structure of 9 pharmacy benefits in the healthcare landscape. 10 Q. And are you -- are you referring to the 11 tiering structure of formularies? 12 A. That's part of it. 13 Q. Have you previously testified about the 14 pharmacy benefit as it relates to generic drugs? 15 A. Some of my previous testimony does bear on 16 generics. 17 Q. What aspects of the generic drug pharmacy 18 benefit have you previously testified about? 19 A. I'm not sure if I could specify other than 20 that generic drugs are covered under pharmacy 21 benefits. Sometimes pharmacy benefits will favor 22 one drug or another. Cost considerations and 23 efficacy are some considerations. 24 Q. Have you ever previously provided 25 testimony about the economic value of certain</p>
<p style="text-align: right;">Page 247</p> <p>1 have been discussing with my colleague all day, 2 would that be accurate that all of those activities 3 would fall under something called a medical benefit 4 of a commercial health insurance? 5 A. So you're referring to benefits of a 6 commercial -- of a -- of a health insurance plan; is 7 that right? 8 Q. Yes, I am. 9 A. Okay. That makes sense. 10 Q. And -- and so would you understand all of 11 those activities that you have been discussing all 12 day to be activities that fall under the medical 13 benefit of a commercial health insurance plan? 14 A. Correct. 15 Q. What is your understanding, then, of the 16 pharmacy benefit associated with a commercial health 17 insurance plan? 18 A. So whereas medical benefit reimburses 19 care -- medical care, including such as office 20 visits or other medical services that are provided, 21 a pharmacy benefit would reimburse the cost of 22 drugs. 23 Q. Now, I understand from your discussions 24 earlier today that you have provided expert 25 testimony in a variety of cases. I'm going to ask</p>	<p style="text-align: right;">Page 249</p> <p>1 generic prescription drugs to consumers? 2 A. No. 3 Q. Have you ever previously testified about 4 the economic value of certain generic prescription 5 drugs to third party payors? 6 A. I haven't testified on that, no. 7 Q. Have you ever provided any testimony about 8 the costs of generic prescription drugs paid by 9 consumers at the pharmacy point of sale? 10 A. I have not testified on that. 11 Q. Have you ever previously testified about 12 the costs of generic prescription drugs paid by 13 third party payors at the pharmacy point of sale? 14 A. I'm not sure. 15 Q. Have you ever provided any testimony about 16 the generic drug approval process? 17 A. Not directly. It may have been touched 18 upon in the context of discussing generic drugs. 19 Q. Have you ever provided any direct 20 testimony about the food and drug cosmetics act? 21 A. No. 22 Q. Have you ever provided any direct 23 testimony about the Drug Supply Chain Security Act? 24 A. No. 25 Q. In your academic life, as it were, have</p>

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1 you ever conducted any research on the food and drug
2 cosmetics act?
3 A. No.
4 Q. Have you ever conducted any research on
5 the Drug Supply Chain Security Act?
6 A. No.
7 Q. Have you ever worked on any FDA task
8 forces related to the approval and regulation of
9 generic prescription drug products?
10 A. No.
11 Q. Have you ever worked as an advisor to the
12 FDA's Office of Generic Drugs?
13 A. Not in that office, no.
14 Q. Which office with the FDA have you worked
15 for?
16 A. I believe that is in -- on my CV. Under
17 Other Professional Positions on page A-2.
18 Q. Yes, I see it.
19 It looks like you worked for the Center
20 for Devices and Radiological Health?
21 A. Yes.
22 Q. And also, you worked in the -- as the --
23 in the White House Office of Science and Technology
24 Policy; is that right?
25 A. In the office of planning and analysis at

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1 the Center for Drug Evaluation and Research.
2 Q. Great.
3 In the context of your work as a staff
4 fellow with the office of planning and analysis for
5 CDER, as I will shorten it to get us through this,
6 what -- what sort of activities did you engage in?
7 A. In various policy analyses I worked with a
8 group of economists, mostly, who were in this
9 office. I -- some of the issues that we analyzed
10 were ways to surveil for potential drug side effects
11 and potential safety -- kind of prescription drug
12 safety programs to -- to ensure that the drugs were
13 being safely used.
14 Q. Did any of this work relate to potentially
15 counterfeit or illegitimate drugs?
16 A. No.
17 Q. Did any of this work with the FDA relate
18 to potentially adulterated or misbranded drugs?
19 A. No.
20 Q. Throughout your report, you use the term
21 "affected valsartan."
22 In your own words, how do you define
23 "affected valsartan"?
24 A. I believe that's in paragraph 11 of my
25 report, "valsartan products that were recalled due

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1 to possible nitrosamine impurity."
2 Q. So your term "affected valsartan" only
3 relates to the valsartan products which were
4 recalled; is that right?
5 A. Which were eventually recalled, I believe.
6 I think that any valsartan -- valsartan that had the
7 possibility of a nitrosamine impurity -- again, I'm
8 not a -- I haven't read so much on the -- on the
9 exact sequence of events here, but I believe that
10 valsartan products that had the potential for
11 nitrosamine impurities were eventually recalled.
12 Q. Are you aware that there were valsartan
13 products manufactured by the defendants in this
14 litigation that had expired by the time of the
15 recall and therefore were not part of the scope of
16 the recall?
17 A. I'm not aware of that. That wasn't
18 something that I looked into in great detail.
19 Q. So your report makes no opinion or takes
20 no opinion about products manufactured by the
21 defendants which were expired and never recalled by
22 the FDA; is that right?
23 MR. STOY: Object to the form.
24 Mischaracterizes testimony.
25 THE WITNESS: Can you say that again?

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1 BY MS. HILTON:
2 Q. Sure. It's a confusing question.
3 Does -- do you -- do you have any opinion
4 about valsartan products that were manufactured by
5 the defendants but which expired before the FDA's
6 recall?
7 A. Were these products ever used by patients?
8 Q. They were.
9 A. What do you mean by "expired"? So they
10 were -- they -- they were expired in the patients'
11 hands or they were prescribed to patients after they
12 had expired?
13 Q. So as I understand it, for some period of
14 time between 2012 and let's call it 2016 or 2017,
15 there were many valsartan products that bore unique
16 NDC codes that were dispensed to patients at the
17 point of sale that were manufactured by the
18 defendants in this litigation.
19 At the time of the FDA recall, many of
20 these products had expired and had already been
21 consumed by the patients and therefore, were not
22 within the scope of the FDA's recall list.
23 And so my question is -- you know, and
24 perhaps I can ask it a different way.
25 Did you expand your analysis to include

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1 those products which were not a part of the FDA's
2 recall list but were nevertheless manufactured by
3 the defendants, you know, from 2012 until 2018?
4 A. So these include drugs that were actually
5 consumed by consumers before the recall, before it
6 was known that nitrosamine -- before that -- before
7 nitrosamine impurities were known; is that right?
8 Q. Correct.
9 A. I believe I do consider those drugs.
10 Q. And how did you identify the NDC codes
11 associated with those drugs?
12 A. I believe the NDC codes are linked to the
13 manufacturer of the drugs. So we would look for
14 valsartan -- we have a list of -- in my report I
15 believe I do describe how we identified the NDC
16 codes.
17 So for -- this is kind of looking at
18 footnote 23.
19 It says, "For my analyses in this report,
20 I used the list of NDC's identified as recalled on
21 the FDA's website to determine 'affected valsartan'
22 products."
23 So these are -- this is something I'll
24 have to think about whether the NDC codes -- so the
25 NDC codes are specific for a manufacturer of a -- of

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1 this -- of this -- a manufacturer and a molecule
2 and -- so these are drugs that were eventually
3 recalled but even -- but these NDC codes would have
4 existed before the recall.
5 Q. Correct. And -- and this was actually an
6 attachment to Dr. Conti's report. I was -- I guess
7 I was trying to determine if you used the same NDC
8 list that was used by Dr. Conti in her report or if
9 you used a different list. It looks here like
10 instead you used the FDA recall list; is that right?
11 A. To the best of my understanding right now,
12 yes, but we could check the two lists to -- to -- to
13 figure out whether they're the same or how they
14 differ.
15 Q. Thank you.
16 For the purposes of your report related to
17 Dr. Conti, did counsel ask you to make any
18 assumptions in drafting this report?
19 A. Not to my knowledge.
20 Q. So counsel did not ask you to assume that
21 the affected valsartan was considered adulterated by
22 the FDA?
23 MR. STOY: Object to the form. Calls for
24 a legal conclusion.
25 THE WITNESS: I'm not sure if that

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1 assumption is required. I know I considered that
2 possibility, that affected valsartan contained
3 nitrosamine impurities and that there is even a
4 possibility of cancer risk due to these impurities.
5 BY MR. MIGLIACCIO:
6 Q. So you assume that the affected valsartan
7 contains nitrosamine impurities and that there was a
8 possible cancer risk due to those impurities?
9 MR. STOY: Objection. Mischaracterizes
10 his testimony.
11 THE WITNESS: I considered the possibility
12 that affected valsartan contained nitrosamine
13 impurities that could increase the risk of cancer
14 for some patients.
15 BY MR. MIGLIACCIO:
16 Q. You didn't assume that the affected
17 valsartan was considered adulterated by the FDA?
18 MR. STOY: Asked -- asked and answered.
19 THE WITNESS: Can you restate that
20 question?
21 BY MS. HILTON:
22 Q. I'll ask it a little bit more clearly.
23 Did you assume that the affected valsartan
24 was considered adulterated by the FDA?
25 MR. STOY: Objection. Asked and answered.

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1 THE WITNESS: I did consider -- you can
2 see in my report that the FDA -- the actions of the
3 FDA are considered in my report but they're not
4 central to my opinion of the value of valsartan.
5 BY MS. HILTON:
6 Q. And looking at your report, you actually
7 never use the term "adulterated"; is that fair to
8 say?
9 A. I believe I have -- I don't use that term.
10 I say valsartan with impurities. I am not an expert
11 to tell the difference between the term of
12 "impurity" versus "adulterated."
13 Q. So you're not providing any expert
14 testimony about adulteration generally; is that fair
15 to say?
16 A. Adulteration versus impurity, I don't know
17 any difference between the words.
18 Q. For the purposes of your report, did you
19 assume that the affected valsartan was manufactured
20 in compliance with all regulations, including
21 Current Good Manufacturing Practices?
22 A. Can you ask that question again?
23 Q. Sure.
24 For the purposes of your report, did you
25 assume that the affected valsartan was manufactured

<p style="text-align: right;">Page 258</p> <p>1 in compliance with all regulations, including 2 Current Good Manufacturing Practices? 3 A. I don't think so. And I don't think that 4 assumption is necessary for my opinions. 5 Q. Why don't you think that assumption was 6 necessary for your analysis of Dr. Conti's report? 7 A. Because for the claim of worth -- the 8 worth of valsartan, I am considering what does that 9 valsartan do. I -- I'm considering the benefits of 10 valsartan in terms of blood pressure control and in 11 terms of treating heart failure. And I'm 12 considering the possibility of a cancer risk. 13 Whether the valsartan was manufactured in 14 a certain way and whether it met certain 15 regulations, whether supply was allowed by the FDA 16 or not, that is not something that I considered 17 relevant for the assessment of worth. 18 Q. You are aware, however, that Dr. Conti's 19 value and opinion about the value of the affected 20 valsartan hinges upon the fact that the valsartan 21 was considered adulterated because it was 22 manufactured in a way that did not comply with 23 Current Good Manufacturing Practices, correct? 24 A. I'm aware of her opinion on that, yes. 25 Q. So no aspect of your particular report</p>	<p style="text-align: right;">Page 260</p> <p>1 affirmatively. 2 Are you offering any opinions about the 3 pharmacy benefit structures and the cost paid by 4 consumers or TPPs at the point of sale for affected 5 valsartan? 6 A. That information is not central to my 7 opinion. Although the idea of costs and revenues 8 and profits to various parties is something within 9 economic -- my economic expertise. 10 Q. But you're not offering any of those 11 opinions in this report for this purpose today? 12 A. Correct. 13 Q. Right? 14 A. Correct. 15 Q. In your -- are you offering any opinions 16 on a drug manufacturer's obligation to comply with 17 Current Good Manufacturing Practices? 18 A. No. 19 Q. Are you offering any opinions on contracts 20 which may impact the amount paid for affected by -- 21 for affected valsartan by any TPP? 22 A. No. 23 Q. I would like to talk to you about getting 24 into the context of a report which I believe was 25 previously marked as Exhibit 2.</p>
<p style="text-align: right;">Page 259</p> <p>1 directly addresses that opinion; is that fair to 2 say? 3 MR. STOY: Object to the form. 4 THE WITNESS: I think it's fair to say 5 that I don't agree with that framework of assessing 6 value. 7 BY MS. HILTON: 8 Q. Before we get into your proposed framework 9 of value, let's make sure that I understand the sort 10 of limitations of your opinion as it relates to the 11 economic value of the prescription drugs. 12 You're not offering any opinions about the 13 data sources used by Dr. Conti in her calculation of 14 damages, correct? 15 A. I'm not commenting on the data sources 16 because my primary opinion is at odds with her 17 framework. 18 Q. You're likewise not offering any opinions 19 on pharmacy benefit structures and the cost paid by 20 consumers or TPPs at the point of sale for the 21 affected valsartan that was dispensed at the 22 pharmacy, correct? 23 A. Can you restate that? 24 Q. Sure. 25 Are you offering -- I'll put it more</p>	<p style="text-align: right;">Page 261</p> <p>1 A. Uh-huh. 2 Q. I'd like to talk to you about 3 paragraph 133 of your report, if you'd like to flip 4 there. 5 A. Okay. 6 Q. And in this paragraph you are discussing 7 the -- let's call it supply and demand framework of 8 Dr. Conti's opinion. 9 A. Uh-huh. 10 Q. And you write, starting in the middle of 11 that paragraph, "The implementation of her approach 12 relies on faulty reasoning. Dr. Conti asserts that 13 'according to economic theory, for a consumer 14 product to have economic value, demand for the 15 product must exist and supply must be allowed to 16 meet demand.' However, the demand curve alone 17 speaks to a product's economic value and is based on 18 each patient's and TPP's willingness to pay for a 19 drug." 20 Do you see that? 21 A. Yes. 22 Q. And then to support that economic theory 23 you cite to a -- let's call it a -- a chapter or a 24 textbook or some sort of treatise; is that right? 25 A. Yes.</p>

<p style="text-align: right;">Page 262</p> <p>1 MS. HILTON: I am going to mark for the 2 record --and which -- what exhibit are we on? 3 THE WITNESS: 7. 4 MS. HILTON: Yeah. Exhibit 8, I think. 5 THE WITNESS: Okay. 6 MS. HILTON: I am going to mark as 7 Exhibit 8 this citation footnote 252. 8 (Whereupon, Chan Exhibit 8 was marked for 9 identification.) 10 BY MS. HILTON: 11 Q. Okay. Let me know when you have Exhibit 8 12 up. 13 A. Yep. 14 Q. Can you tell me what particular section of 15 this chapter you were using to support your opinion 16 that the demand curve alone speaks to a 17 pharmaceutical product's economic value and is based 18 on a patient/TPP's willingness to pay for a drug? 19 A. Okay. So in these pages, there is no 20 supply curve. What we call consumer surplus is very 21 closely related to the economic value. Consumer 22 surplus is the demand curve that lies above the 23 price. 24 Q. Do you -- does this particular chapter 25 relate to pharmaceutical drug products?</p>	<p style="text-align: right;">Page 264</p> <p>1 That's irrelevant. It's only relevant in so far as 2 it affects consumer surplus or the demand curve. It 3 doesn't depend on a supply curve. 4 Q. If we look at the second page of this 5 particular PDF, it says, "To calculate the aggregate 6 consumer surplus in a market," does that not 7 indicate that there must be the product on the 8 market? 9 A. You can also talk about consumer surplus 10 for a good that doesn't yet exist. It does not 11 presuppose that there must be a market for it. It 12 happens to say in the market, but that's not a 13 requirement. 14 Q. Where in this particular chapter does it 15 indicate that it is not a requirement of the product 16 at issue for consumer surplus must not be in the 17 market? 18 A. In this chapter there is no mention of a 19 supply curve. 20 Q. So that is the basis for your statement -- 21 A. It doesn't require a supply curve. 22 Usually we do have a market and that's why this is 23 kind of the usual setting but when you're talking 24 about willingness to pay and when you're talking 25 about utility you don't need a market.</p>
<p style="text-align: right;">Page 263</p> <p>1 A. This is an economic -- an economics 2 textbook which is quite general when we talk about 3 demand curves and supply curves. This particular 4 chapter uses a very -- it uses any -- it uses just a 5 random example of rock concert tickets but the focus 6 is not about rock concert tickets. 7 Q. Does this chapter in the discussion of the 8 consumer surplus presuppose that all of the items 9 that are subject to this consumer surplus analysis 10 are items that can legally be on the market? 11 A. There's no presupposition of that. 12 Q. So this would relate to anything, even 13 products that are illegal to sell on the market? 14 A. It could have been illegal rock concert 15 tickets or it could be -- 16 Q. I'm sorry. 17 A. -- or -- go ahead. 18 Q. No, continue. 19 A. They could have been illegal tickets. 20 Q. Where does it say that it -- that the 21 tickets could have been illegal? 22 A. It doesn't say it in the text, but if you 23 were to ask any economist -- well, I guess maybe if 24 you were to many economists -- Dr. Conti's an 25 economist -- it does not presuppose the legality.</p>	<p style="text-align: right;">Page 265</p> <p>1 Q. Would you agree that the market for 2 concert tickets is very different than the highly 3 regulated market of prescription drugs? 4 A. Yes, but this chapter is not about concert 5 tickets. This chapter is a general economic 6 textbook on economics, on microeconomics, and this 7 chapter is about consumer surplus which applies to 8 both concert tickets and prescription drugs. 9 Q. If we look at the next sentence of 10 paragraph 133 you go on to write -- I think this is 11 what you were alluding to before -- that sometimes 12 there could be a value for a product that is not yet 13 on the market. 14 You write, "Consider a pill that cures 15 cancer, there is no supply for such a pill as one 16 has not been invented yet, but it is certainly 17 possible to consider the patient and TPP's 18 willingness to pay for such a pill and the inherent 19 economic value such an innovation would provide." 20 Do you see that? 21 A. Yes. 22 Q. In this particular example of the 23 hypothetical pill that cures cancer, are you 24 assuming that the pill at issue has been 25 manufactured in compliance with good manufacturing</p>

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1 practices?
2 A. No.
3 Q. So it is your opinion that consumers and
4 TPPs would be willing to pay for a pill that has not
5 been manufactured in compliance with good
6 manufacturing practices and could not assure that
7 it's safe?
8 A. I think it's certainly possible.
9 Q. You don't have any evidence to associate
10 that, correct?
11 A. I think it's -- I would say it's common
12 sense. You are pay -- you are willing to pay for
13 the benefits of a good. If there is some
14 uncertainty about the benefits of the good, that's
15 why things like, you know, good manufacturing
16 processes, that's why those might be valuable, but
17 if -- in this hypothetical world where we already
18 knew that this pill would cure cancer, we wouldn't
19 have to know whether it was manufactured under good
20 manufacturing practices.
21 Q. Do you believe that generic drug products
22 that are manufactured in such a way that the product
23 contains glass are valuable?
24 A. That's a hypothetical question. I think
25 it would depend on the circumstance.

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1 Q. Are you -- have you ever heard of a
2 generic drug manufacturer named Ranbaxy?
3 A. Can you restate that question?
4 Q. Have you ever heard of a generic drug
5 manufacturer named Ranbaxy?
6 A. I might have. I don't recall right now.
7 Q. If I were to tell you that Ranbaxy
8 manufactured generic products that contained
9 glass --
10 MR. STOY: Are you --
11 (Whereupon, a brief discussion off the
12 record.)
13 BY MS. HILTON:
14 Q. If I were to tell you that Ranbaxy
15 manufactured generic products that contained glass
16 and that this -- that these products had to be
17 recalled from the market, would it be your position
18 that these glass-contaminated generic products had
19 value?
20 A. I don't know enough about this situation
21 to say anything. It's possible that they could
22 still have value, but I don't know enough.
23 Q. What would you need to know in order to
24 assess whether the drug had value or didn't have
25 value?

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1 A. I would need to know the medical benefits
2 of taking that drug and the medical harms of taking
3 that drug.
4 Q. Do you agree with Dr. Conti's conclusion
5 that there exists substantial asymmetry of
6 information about the safety and quality of
7 prescription drugs between the manufacturers of
8 those drugs and the patients who purchase and
9 consume those drugs?
10 MR. STOY: I'll object to the extent it's
11 beyond the scope of Dr. Chan's analysis.
12 But you can answer.
13 THE WITNESS: I don't have a particular
14 opinion on that. I think it's possible. But I
15 think it might depend.
16 BY MS. HILTON:
17 Q. What would it depend on?
18 A. Depends on what the product is. It
19 depends on -- so you -- can -- can you just restate
20 the question? It's asymmetric information between
21 the manufacturers of a drug and -- and who else?
22 Q. And the patients who purchase and consume
23 those drugs.
24 MR. STOY: Same objection.
25 THE WITNESS: It really depend -- I mean,

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1 there are different types of asymmetric information,
2 right, the patient may have more information about
3 their medical condition than the manufacturer. The
4 manufacturer might have more information about how
5 they manufactured the drug. So the information is
6 not symmetric in different ways.
7 BY MS. HILTON:
8 Q. Is that a topic of upon which you'll opine
9 in your report?
10 A. I don't believe that's a central -- that's
11 a central element required for my opinions in the
12 report. I think ultimately, at the end of the day,
13 the value of a drug is the medical benefit weighed
14 against any harms of the drug.
15 Q. You describe that -- in the body of your
16 report that in order, as you see it, to calculate
17 the economic value of a product to a particular
18 plaintiff or patient, you would need to know
19 something you describe as the ex-ante value as well
20 as the ex-post value; is that right?
21 A. In my report, I describe ex-ante value and
22 ex-post value. I just -- I describe that because
23 there are different concepts. There are different
24 concepts of value. It depends on when you're asking
25 about value.

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1 And this is particularly important when
2 there's uncertainty about what actually is in the
3 drug. Even before we knew that there might be
4 impurities in the valsartan drug, there is still an
5 ex-ante value that could account for the possibility
6 of this impurity. And then after we find out about
7 the possibility of impurity in some of the lots, the
8 value of the drug could be updated in ex-post way.

9 Q. You -- you testified that there was the --
10 that it was possible somebody might know about the
11 impurity at the time that they purchased the drug
12 and that would be a part of its ex-ante value?

13 A. They might know about a possibility of
14 impurity.

15 Q. What evidence did you review in this case
16 that demonstrated that any one particular patient
17 had any inkling that their valsartan might contain
18 carcinogens?

19 A. So as one consideration -- one piece of
20 evidence that I -- I mention in the report is that
21 at one point we did know about impurities in
22 valsartan and the FDA recommended patients to
23 continue taking their valsartan. That's one
24 specific -- that's one specific instance about --
25 about impurities specifically related to

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1 nitrosamines.

2 But my earlier statement was about the
3 general possibility that we may discover something
4 about a drug that we didn't know. When you purchase
5 something, there's not a hundred percent certainty
6 about what that thing is in general. And you may
7 discover something that nobody else -- nobody knew
8 about this thing that you purchased and it could
9 include the possibility of impurities in general.

10 Q. I want to talk a little about your first
11 statement that the FDA made a statement that people
12 should continue to take their valsartan drugs.

13 You're aware that that statement was made
14 in August 2018, correct?

15 A. Correct.

16 Q. So at that point, all of the -- or most of
17 the manufacturers and the defendants in this case
18 had already recalled all of their product off the
19 market at the time that the FDA made this statement,
20 right?

21 MR. STOY: Object to the form.

22 THE WITNESS: I don't know the timeline.

23 Can you -- can you say that again?

24 BY MS. HILTON:

25 Q. Yeah.

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1 As of August 2018, at the time that the
2 FDA made the statement you just referred to about
3 the possibility of nitrosamine contamination, many
4 of the defendants had started recalling all of their
5 products off the market; isn't that right?

6 A. I don't know all the details but if what
7 you just said is true, then some of them did not
8 recall just yet.

9 Q. But regardless, what the FDA said about
10 the drugs in August of 2018 would have no bearing
11 whatsoever on the ex-ante value of a drug purchased
12 from 2012 until June of 2018, right?

13 A. That statement would have bearing for
14 people who purchased the drug after the statement.

15 Q. So would not relate to any of the
16 purchases prior to August of 2018?

17 A. I think it still relates to whether people
18 would purchase before that time in the sense that
19 that statement is talking about potential value.
20 It's talking about the medical benefits of taking
21 that drug and that would be in the consideration of
22 people who purchased it before.

23 What I was saying in the second part of my
24 response about the possibility of impurities is that
25 there's always the possibility that something --

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1 there might be something about that drug that you
2 don't know just yet and that's what I'm calling the
3 ex-ante value.

4 Q. How does your opinion regarding the
5 ex-ante value of the affected valsartan change in
6 light of the fact that there was valsartan on the
7 market that did not contain nitrosamines?

8 A. I did consider that.

9 Q. How did you consider that?

10 A. So when you're talking about a demand
11 curve, the demand curve incorporates other products
12 that are already in the market.

13 Q. So is the ex-ante value of a valsartan
14 that did not contain nitrosamine manufactured by a
15 manufacturer that is not a defendant in this case
16 different than the ex-ante value of the affected
17 valsartan?

18 A. Can you say that again?

19 Q. Is the ex-ante value of the uncontaminated
20 valsartan manufactured by manufacturers who are not
21 defendants in this case different than the ex-ante
22 value of the affected valsartan at issue in this
23 litigation?

24 A. And by ex-ante you mean before we knew
25 which manufacturers were associated with affected

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1 valsartan; is that right?

2 Q. Correct.

3 A. I can't say whether they're exactly the

4 same. They could still differ. I don't know the

5 other considerations that might differentiate

6 different manufacturers before it was known which

7 ones were linked to affected valsartan.

8 Q. In your discussion of the ex-ante value of

9 affected valsartan, you delineated a list of factors

10 that you would look at to determine the value; is

11 that right?

12 A. Can you point me to the paragraph that

13 you're talking about?

14 Q. Sure.

15 134.

16 A. Uh-huh.

17 Q. From an economics perspective, how would

18 you go about incorporating these values and these

19 factors in a calculation to determine a prescription

20 drug's ex-ante value?

21 A. That is not a core -- that's not a core

22 analysis that I did in this report, although I talk

23 about it. The core opinion of this report is

24 whether we can say that affected valsartan is

25 worthless.

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1 Q. So you have no opinion whatsoever on how

2 to actually go about calculating the ex-ante value

3 of the affected valsartan; is that right?

4 A. I have some ideas --

5 MR. STOY: Objection to form.

6 THE WITNESS: -- but I don't know if

7 they're kind of -- if they're thought through at the

8 proper level that I would be willing to offer them

9 at this deposition.

10 BY MS. HILTON:

11 Q. Have you ever conducted a mathematical

12 calculation of a generic prescription drug product's

13 ex-ante value before?

14 A. I personally have not but I think that

15 there are several ways in which you could address

16 this.

17 Q. What are those ways?

18 A. So without having thought in great detail

19 for this deposition, there are ways to value what

20 consumers -- value consumers' utility in terms of

21 different health outcomes. It would -- you can

22 incorporate the value of getting cancer with the

23 value of controlling hypertension. The value of

24 treating heart failure. There are methods to value

25 those things and if -- that's one way to kind of --

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1 to perhaps to get at these ex-ante values

2 incorporating any uncertainty.

3 There are possibly other ways to do this

4 that I haven't thought to to the level of detail

5 that I think it would require for this deposition.

6 Q. Have you ever read any literature about

7 conducting the mathematical calculation for the

8 ex-ante value of a generic prescription drug?

9 A. I'm aware of literature that -- that uses

10 the approach that I just described to you. And that

11 approach could be applied to the value of a generic

12 prescription drugs.

13 Q. Is that literature cited in your report?

14 A. That's -- it's possibly cited in my

15 report. I can't recall. This is not a -- as I

16 said, my report primarily addresses the claim of

17 whether valsartan is worthless, not how one would

18 conduct an economic evaluation of the worth.

19 Q. Well, you, yourself, have never actually

20 endeavored to conduct such a calculation or

21 evaluation of a generic prescription drug's ex-ante

22 value, correct?

23 A. Specifically --

24 MR. STOY: Asked and answered.

25 THE WITNESS: Go ahead, Frank.

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1 MR. STOY: I just objected to asked and

2 answered.

3 You can go ahead.

4 THE WITNESS: That's a very specific

5 question that you asked, whether I endeavored to

6 calculate the ex-ante value before an information

7 revelation of a generic prescription drug.

8 It's hard for me to kind of answer whether

9 I have done cost-effectiveness analyses for analyses

10 of patient utility that could bear on that exact

11 specific question, but I have done economic analyses

12 that value different patient health outcomes and

13 weighed them against each other.

14 BY MS. HILTON:

15 Q. So the answer is no, you haven't conducted

16 a mathematical calculation to determine the ex-ante

17 value of a prescription generic drug; is that right?

18 A. It's possible that I have. I just can't

19 remember.

20 Q. After determining the ex-ante value of a

21 prescription drug, you write that in order to figure

22 out the -- I guess the injury to a particular

23 plaintiff you have to then ascertain the ex-post

24 value of that product.

25 What is your definition of ex-post value?

<p style="text-align: right;">Page 278</p> <p>1 A. What I refer to here as ex-post value is 2 the value that you have after the information 3 revelation. 4 But I think it's important to note that 5 there are many different steps of information 6 revelation that could be possible. 7 There is information revelation that you 8 consumed a drug that could contain nitrosamines. 9 And there's further revelation of you may know 10 whether or not you had a lot that had nitrosamines 11 in it. And then ultimately you would need to know 12 whether you suffered cancer as a result of 13 nitrosamines. That could be an event later down the 14 road. There are many different kind of points in 15 the timeline at which you might have different 16 values. 17 Q. So is it fair to say there's no real 18 concrete way to actually calculate a -- the effect 19 of valsartan's ex-post value? 20 A. No, it's not fair to say that. 21 Q. Why not? 22 A. There is a framework that you could 23 undertake -- and this is not something that I -- 24 again, the key point of my report is that I'm 25 rejecting the idea that anybody who consumed</p>	<p style="text-align: right;">Page 280</p> <p>1 actually have knowledge of that risk? 2 A. No. 3 Q. Why not? 4 A. A risk aversion does not require knowledge 5 of risk. It tells you what -- what is the expected 6 utility of somebody given uncertainty in the future 7 and this person could have many different 8 realizations of whether they get something that's 9 an -- like an -- what would be called a negative 10 shock to their utility versus a positive shock to 11 their utility. 12 All they need to know in order to 13 calculate risk aversion is how that person's utility 14 varies across different states of the world. 15 Q. So your testimony is that risk aversion 16 and the idea of risk does not require a person to 17 actually have knowledge of the risk; is that right? 18 A. To measure risk aversion you don't need -- 19 you don't -- you don't need to know the person's 20 knowledge. It does not require a person's knowledge 21 of the risk to measure risk aversion. 22 In order to calculate somebody expected 23 value -- expected willingness to pay at a given 24 point in time you would need to know what are the 25 possible states of the world in the future and you</p>
<p style="text-align: right;">Page 279</p> <p>1 affected valsartan had a value of zero. That is the 2 key point that I'm saying. 3 But if you needed to calculate exactly 4 what somebody's ex-post value would be, as I 5 mentioned, there are methods to use health outcomes 6 and methods to incorporate uncertainty to arrive at 7 a willingness to pay. 8 Q. Have you ever conducted a mathematical 9 calculation of a generic drug's ex-post value? 10 A. I think my answer would be similar to your 11 question about whether I've conducted a mathematical 12 analysis to calculate the ex-ante value of a drug. 13 It's possible that I have. I can't really comment 14 at this point. The methods that you would use to do 15 such a thing I have done. 16 Q. If we look at the second-to-last sentence 17 in paragraph 137, you were talking about risk 18 aversion in this paragraph, and you write, "Second, 19 any reduction in economic value depends on a 20 patient's level of risk aversion, which has been 21 shown to vary across individuals." 22 Do you see that? 23 A. Uh-huh. Yes. 24 Q. When discussing risk aversion, isn't it 25 necessary that a person who is averting risk</p>	<p style="text-align: right;">Page 281</p> <p>1 would need to know the risk aversion but to know 2 their risk aversion you don't need patient knowledge 3 of various events in the future. 4 Q. But you do agree that the additional risk 5 that nitrosamines in the affected valsartan could in 6 some instances reduce the economic value of the 7 drug, right? 8 A. In some instances, yes. 9 MS. HILTON: Can we go off the record. I 10 may be close to finish and I just want to check in 11 with my colleagues. 12 THE VIDEOGRAPHER: Okay. We're off the 13 record at 4:03 p.m. Pacific time. 14 (Whereupon, a brief recess was taken.) 15 THE VIDEOGRAPHER: We are back on the 16 record. The time is 4:09 p.m. Pacific time. 17 BY MS. HILTON: 18 Q. Dr. Chan, have you ever prescribed 19 valsartan to a patient? 20 A. Yes. 21 Q. How did you personally become aware of the 22 recall of the affected valsartan products? 23 A. I became aware of the recall through this 24 case. 25 Q. So prior to this case, you had no</p>

<p style="text-align: right;">Page 282</p> <p>1 knowledge that the FDA had initiated an 2 unprecedented classwide recall of the affected 3 valsartan? 4 MR. STOY: Object to the form. 5 THE WITNESS: As a hospitalist, I don't 6 decide which valsartan, which -- specifically which 7 NDC gets delivered to a patient, gets dispensed to a 8 patient. I write valsartan, the dose, the 9 frequency, and I don't concern myself with whether 10 it's branded or generic and if it's generic, which 11 type of valsartan it is. So there's no reason for 12 me to pay attention to that. 13 BY MS. HILTON: 14 Q. And do you not concern yourself with these 15 things because the generic is supposed to be the 16 same as the branded drug? 17 MR. STOY: Object to the form. 18 THE WITNESS: That's not the reason that I 19 don't pay attention to these things. The reason 20 that I don't pay attention to these as a 21 hospitalist, personally as a clinician, is that I 22 don't determine which of these drugs, which NDC code 23 is going to be dispensed to a patient for whom I 24 prescribe valsartan. 25</p>	<p style="text-align: right;">Page 284</p> <p>1 BY MS. HILTON: 2 Q. And at what point in your education did 3 you learn about the impurities that may be present 4 in generic drugs? 5 A. I'm not sure if I remember the time in my 6 education. But I think it's in some ways common 7 sense. You know that generic drugs are made by 8 different manufacturers. You know that they're not 9 exactly the same. The requirement of generic drugs 10 is that they have the same active ingredient. It's 11 not required that they're exactly the same. 12 And so it follows naturally that there 13 might be things that differ between generic drugs 14 and branded drugs and that we don't know all of 15 these, including the generic manufacturers at the 16 time, don't know all of these things at this point 17 and some of these things could be revealed later on. 18 Q. Would it surprise you to know that one of 19 the generic manufacturers in this case had knowledge 20 that their valsartan contained nitrosamines a year 21 before they were actually recalled from the market? 22 MR. STOY: Object to the form. Beyond the 23 scope. Mischaracterizes. 24 THE WITNESS: I have no knowledge of that. 25 MR. STOY: Mischaracterizes the evidence.</p>
<p style="text-align: right;">Page 283</p> <p>1 BY MS. HILTON: 2 Q. Just generally, though, in your practice 3 as a physician do you have an expectation that the 4 generic products are the same as the branded 5 reference listed drugs? 6 MR. STOY: Objection. Beyond the scope of 7 his report. 8 You can answer. 9 THE WITNESS: This is not a -- this is 10 not -- this is not within the scope of my report. 11 Would you like me to comment on -- I'm not sure. 12 BY MS. HILTON: 13 Q. Yeah, I'm just asking you, as a physician, 14 you have that expectation that the generic drugs are 15 the same as the reference listed brand drugs? 16 MR. STOY: Object to the form. 17 Go ahead. 18 THE WITNESS: I think my main expectation 19 is that they should contain the same active 20 ingredient. I know that there is a process by which 21 we might identify impurities in drugs and recall 22 drugs. And that there is no guarantee that a 23 generic drug will be exactly the same as a branded 24 drug. 25</p>	<p style="text-align: right;">Page 285</p> <p>1 Go ahead. 2 THE WITNESS: I have no knowledge of that. 3 I'm not sure if I can comment on that. 4 BY MS. HILTON: 5 Q. Okay. Have you ever monitored any 6 patients for cancer? 7 A. No, not -- let me just -- let me clarify. 8 I have in the past ordered screening tests 9 for cancer. My current clinical responsibilities 10 does not primarily focus on screening for cancer as 11 a hospitalist. 12 Q. What screening tests did you order for 13 cancer? 14 A. In primary care you could order a number 15 of screening tests such as Pap smears or 16 colonoscopies. 17 Q. Aside from the opinions that are contained 18 within your report, do you intend to offer any other 19 opinions in this litigation? 20 A. I don't have any plans to do so right now. 21 MS. HILTON: Thank you, Doctor. I have no 22 further questions. 23 MR. STOY: Thank you. 24 Let's go off the record. 25 THE VIDEOGRAPHER: Off the record for the</p>

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1 day or does anyone have anything else?
 2 MR. STOY: We may have some follow-up
 3 questions. I want to take ten minutes.
 4 THE VIDEOGRAPHER: No problem.
 5 We're off the record at 4:15 p.m.
 6 (Whereupon, a brief recess was taken.)
 7 THE VIDEOGRAPHER: We are back on the
 8 record. The time is 4:26 p.m. Pacific team.
 9 EXAMINATION
 10 BY MR. STOY:
 11 Q. All right. Dr. Chan, good afternoon
 12 again. Welcome back. I know it's been a long day
 13 so I'm going to be brief but I do have a few
 14 follow-up questions to ask you, okay?
 15 A. Okay.
 16 Q. My first question is, as a matter of
 17 economics, can you explain the interplay between
 18 price and value?
 19 MS. HILTON: Objection to form.
 20 BY MR. STOY:
 21 Q. Go ahead.
 22 A. Sure.
 23 Value relates to the utility that somebody
 24 would get from a product and together this forms the
 25 demand curve. Price is something when you have a

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1 market and you have supply and where demand meets
 2 supply that's where you have price. So you can have
 3 value even if there's no market and even if there's
 4 no supply.
 5 Q. Are price and value considered
 6 interchangeable terms in economics?
 7 A. No.
 8 Q. Is economic value the same thing as
 9 equilibrium price?
 10 A. No.
 11 Q. In paragraph 44 of Dr. Conti's report, and
 12 I believe it's maybe Exhibit 3, you can pull it up
 13 if you want to, but I'm going to read a statement.
 14 She says, and I quote, According to
 15 economic theory, for a consumer product to have
 16 economic value, demand for the product must exist
 17 and supply must be allowed to meet demand.
 18 Do you agree with that statement by
 19 Dr. Conti regarding economic theory?
 20 A. No, I don't agree with that. That is not
 21 consistent with what I have described as economic
 22 theory and the relationship between price and value.
 23 Q. Can a product have economic value even if
 24 there is no equilibrium price in the market?
 25 A. Yes.

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1 Q. Is willingness to pay the only thing to
 2 consider in determining economic value?
 3 A. Yes. Willingness to pay and economic
 4 value are synonymous.
 5 Q. Dr. Chan, you were shown an article that
 6 you had previously written in the New England
 7 Journal of Medicine. I believe it was Exhibit 5.
 8 Do you remember that?
 9 A. Yes.
 10 Q. And then you were also shown some comments
 11 that were received that were sent to the author. I
 12 believe that was Exhibit 6.
 13 Do you remember that?
 14 A. Yes.
 15 Q. Is it uncommon for peer-reviewed
 16 publications for the authors to be sent comments by
 17 people?
 18 A. I don't know how common it is. But in
 19 this case, this was a comment that was a bit
 20 ancillary to the main analysis and we acknowledged
 21 the comment. And the article itself, I think the
 22 main points that we made in the article itself are
 23 still valid. The -- it's also -- it also bears
 24 mentioning that the comment didn't really make a
 25 point about averages versus other types of moments

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1 of a statistical distribution.
 2 Q. Did the New England Journal of Medicine
 3 retract your article after those comments were
 4 submitted?
 5 A. No.
 6 Q. Was the article ever retracted?
 7 A. No.
 8 Q. Now, I want you to go back to your report,
 9 Dr. Chan. And specifically, I want you to look at
 10 paragraph 117.
 11 Are you there?
 12 A. Okay. Yep.
 13 Q. Do you recall earlier you were asked some
 14 questions with regard to the use of averages?
 15 A. Yes.
 16 Q. Why is Dr. Song's use of averages in his
 17 report inappropriate, in your opinion?
 18 MS. HILTON: Objection to form.
 19 THE WITNESS: And I want to clarify that
 20 averages are not in and of themselves a bad thing.
 21 It depends on how you're using the averages and as I
 22 said during the deposition, which sample you're
 23 getting the average from and what purpose you're
 24 using the average for.
 25 The problem with Dr. Song's use of an

<p>Page 290</p> <p>1 average from some publication that looks at another 2 population, probably a general population, comparing 3 private insurance prices and Medicare prices, is 4 that that average might not be applicable to the 5 class at hand, which by definition, would have had 6 to be patients who took valsartan. And it's 7 possible that that average could be wildly off. 8 MR. STOY: Okay. Thank you, Dr. Chan. I 9 have no further questions. 10 MS. HILTON: Can we go off the record for 11 a moment. I just want to confer. 12 THE VIDEOGRAPHER: Okay. We're off the 13 record at 4:32 p.m. 14 (Whereupon, a brief recess was taken.) 15 THE VIDEOGRAPHER: We are back on the 16 record at 4:35 p.m. 17 EXAMINATION 18 BY MS. HILTON: 19 Q. Doctor, Mr. Stoy asked you questions about 20 equilibrium price. 21 Do you remember that? 22 A. Yes. 23 Q. What's your definition of equilibrium 24 price? 25 A. Equilibrium price is where supply and</p> <p>Page 291</p> <p>1 demand meet in terms of price. 2 Q. And it's your testimony that a product can 3 have economic value even if there is no equilibrium 4 price in the market? 5 A. Yes. 6 MS. HILTON: I have no further questions. 7 EXAMINATION 8 BY MR. MIGLIACCIO: 9 Q. Doctor, I just have I think one. Maybe -- 10 I thought it was one. We'll see. 11 You -- Mr. Stoy asked you questions about 12 averages in paragraph 117. And you testified 13 that -- that the average might not be applicable to 14 the class at hand and that it's possible that that 15 average could be wildly off, correct? 16 A. Correct. 17 Q. That was your testimony. 18 I just want to confirm you have not, in 19 fact, done any calculations to determine if the 20 average is not applicable to the class at hand or 21 that the average is, in fact, wildly off? 22 A. I think I said during the deposition that 23 I have evidence that it's likely that members of the 24 class will be different than the average population 25 and that there is scope for getting the average</p>	<p>Page 292</p> <p>1 wrong if you just look at variation in prices, which 2 we have done in the report. 3 Q. You have not, in fact, done any 4 calculations, though, to determine if the averages 5 are wildly off or not applicable? 6 A. The other thing I think I've said in the 7 deposition is that I think it would be quite 8 difficult to actually calculate it so I don't think 9 anybody's done any calculations to show me something 10 about what that price would be other than what the 11 overall average is. 12 Q. Including you, you have not done? 13 A. Include me or -- 14 Q. Okay. 15 A. -- anybody else among the plaintiffs' 16 side. 17 Q. Got it. 18 MR. MIGLIACCIO: I have no further 19 questions. Thank you, Doctor. 20 MR. STOY: Nothing further from us. 21 THE VIDEOGRAPHER: Okay. This marks the 22 end of today's testimony of Dr. David Chan. 23 We are off the record at 4:37 p.m. Pacific 24 time. 25 (Whereupon, the deposition was concluded</p> <p>Page 293</p> <p>1 at 4:37 p.m.) 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p>
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<p style="text-align: right;">Page 294</p> <p style="text-align: center;">INSTRUCTIONS TO WITNESS</p> <p>Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.</p> <p>After doing so, please sign the errata sheet and date it.</p> <p>You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.</p> <p>It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.</p>	<p style="text-align: right;">Page 296</p> <p style="text-align: center;">ACKNOWLEDGMENT OF DEPONENT</p> <p>I, _____, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.</p> <p>_____ DAVID C. CHAN, JR., M.D. DATE</p>
<p style="text-align: right;">Page 295</p> <p style="text-align: center;">ERRATA SHEET</p> <p>PAGE LINE CHANGE</p> <p>_____ REASON: _____</p> <p>PAGE LINE CHANGE</p> <p>_____ REASON: _____</p> <p>PAGE LINE CHANGE</p> <p>_____ REASON: _____</p> <p>PAGE LINE CHANGE</p> <p>_____ REASON: _____</p> <p>PAGE LINE CHANGE</p> <p>_____ REASON: _____</p> <p>PAGE LINE CHANGE</p> <p>_____ REASON: _____</p>	<p style="text-align: right;">Page 297</p> <p>STATE OF CALIFORNIA) COUNTY OF YOLO)</p> <p>I, ELAINA BULDA-JONES, a Certified Shorthand Reporter of the State of California, duly authorized to administer oaths pursuant to Section 2025 of the California Code of Civil Procedure, do hereby certify that</p> <p>DAVID C. CHAN, JR., M.D.,</p> <p>the witness in the foregoing deposition, was by me duly sworn to testify the truth, the whole truth and nothing but the truth in the within-entitled cause; that said testimony of said witness was reported by me, a disinterested person, and was thereafter transcribed under my direction into typewriting and is a true and correct transcription of said proceedings.</p> <p>I further certify that I am not of counsel or attorney for either or any of the parties in the foregoing deposition and caption named, nor in any way interested in the outcome of the cause named in said deposition dated the 7th day of March, 2022.</p> <p>ELAINA BULDA-JONES, CSR 11720</p>

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Exhibit 208

REDACTED

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF NEW JERSEY

2

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3

IN RE: VALSARTAN, :MDL NO. 2875
4 LOSARTAN, AND IRBESARTAN :
PRODUCTS LIABILITY :CIVIL NO.
5 LITIGATION :19-2875 (RBK/JS)
:
6 THIS DOCUMENT APPLIES :HON. ROBERT
TO ALL CASES : B. KUGLER

7

- CONFIDENTIAL INFORMATION -
8 SUBJECT TO PROTECTIVE ORDER

8

9

- - -

10 MARCH 10, 2022

11

- - -

12

13 Videotaped remote deposition of LEWIS
14 A. CHODOSH, M.D., Ph.D., taken pursuant to
15 notice, was held via Zoom Videoconference,
16 beginning at 9:15 A.M. (EST), on the above
17 date, before Margaret M. Reihl, RPR, CRR,
18 CCR-NJ.

19

- - -

20

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4 DOLORES DeSALVO, JD, PHR	4 By Ms. Bogdan 230
5 P.O. Box 15141	5 By Mr. Insogna 230
6 Albany, New York 12212-5141	6 EXHIBITS
7 (518) 724-2298	7 NO. DESCRIPTION PAGE
8 rosemarie.bogdan@1800law1010.com	8 1 Notice to Take Videotaped Oral Deposition 15
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10 HOLLIS LAW FIRM	10 3 Invoices and receipts 21
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12 8101 College Boulevard, Suite 260	12 5 Lewis A. Chodosh, M.D., Ph.D. Amended List of Materials Considered 3/8/22 27
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14 (913) 385-5400	14 7 Testing Result of N-Nitrosodimethylamine (NDMA) PRINSTON00273444 to 3479 77
15 Representing the Plaintiffs	15 8 Testing Result of N-Nitrosodimethylamine (NDMA) PRINSTONO0068872 to 8900 86
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Actavis LLC and Actavis Pharma, Inc.	
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2 PIETRAGALLO GORDON ALFANO BOSICK & RASPANTI, LLP	2 NO. DESCRIPTION PAGE
3 BY: CLEM C. TRISCHLER, ESQUIRE	3 9 Deviation Investigation Report by Zhou Xiaohui ZHP00013245 to 13353 91
4 38th Floor, One Oxford Centre	4 10 Exhibit B-Report Dr. Madigan 114
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Huahai U.S., Inc., and Solco	
Healthcare US, LLC	
Also present: Bill Geigert, Videographer	
Mike Kutys, Trial Technician	

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<p>1 EXHIBITS 2 NO. DESCRIPTION PAGE 3 18 Endogenous versus exogenous 4 exposure to N-nitroso 5 compounds and gastric 6 cancer risk in the European 7 Prospective Investigation 8 into Cancer and Nutrition 9 (EPIC-EURGAST) study 202 10 19 Diet Composition Is 11 Associated with 12 Endogenous Formation of 13 N-Nitroso Compounds in 14 Obese Men 205 15 20 Volatile N-Nitrosamine 16 Formation after Intake of 17 Nitrate at the ADI Level 18 In Combination with an 19 Amine-rich Diet 208 20 21 Intragastric formation and 22 modulation of 23 N-nitrosodimethylamine 24 in a dynamic in vitro 25 gastrointestinal model under human physiological conditions 214 22 22 Use of N-nitrosodimethylamine (NDMA) contaminated valsartan products and risk of cancer: Danish nationwide cohort study 219 23 23 N-Nitrosodimethylamine- Contaminated Valsartan and the Risk of Cancer 224 ---</p>	<p>1 BY MS. BOGDAN: 2 Q. Good morning, Dr. Chodosh, we've met before. 3 My name is Rosemarie Bogdan and I represent the 4 plaintiffs in the Valsartan, Losartan, Irbesartan 5 Products Liability Litigation that is pending in the 6 United States District Court, District of 7 New Jersey. 8 I'm going to be asking you some questions 9 today and I would ask if you don't understand the 10 question that I pose to you, that you please let me 11 know that so I have the opportunity to rephrase it. 12 If you answer the question, I'm going to 13 assume that you understood it; is that fair? 14 A. It's fair, with the proviso of I may think 15 that I understood it but that may be different than 16 what you understand it to mean. Not to pick hairs. 17 Q. Okay. Well, if you, for any reason, don't 18 understand or perceive that you don't understand 19 what I'm asking, please let me know that so I have 20 the opportunity to rephrase my question for you, 21 okay? 22 A. Absolutely. 23 Q. Where are you currently located? 24 A. You mean where am I sitting? 25 Q. Yes.</p>
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<p>1 THE VIDEOGRAPHER: Good morning, we 2 are now on the record. My name is 3 Bill Geigert, I'm a videographer for Golkow 4 Litigation Services. Today's date is 5 March 10th, 2022, and the time is 9:15 a.m. 6 This remote video deposition is being 7 held in the matter of Valsartan, Losartan 8 and Irbesartan Products Liability Litigation 9 for the United States District Court for the 10 District of New Jersey. The deponent is 11 Dr. Lewis Chodosh. 12 All parties to this deposition are 13 appearing remotely and have agreed to the 14 witness being sworn in remotely. Due to the 15 nature of remote reporting, please pause 16 briefly before speaking to ensure all 17 parties are heard completely. 18 All counsel will be noted on the 19 stenographic record. The court reporter is 20 Peg Reihl and she will now swear in the 21 witness. 22 LEWIS A. CHODOSH, M.D., Ph.D., having 23 been duly sworn as a witness, was examined 24 and testified as follows: 25</p>	<p>1 A. I am sitting in Greenberg Traurig on 2 Arch Street in Philadelphia. 3 Q. Okay. And is there anyone in the room with 4 you? I'm asking that because we are taking this 5 deposition remote. 6 A. Yes, there is. 7 Q. Okay. Who is in the room with you? 8 A. Nick Insogna and Alyson. And I'm not sure I 9 know Alyson's last name. 10 Q. And is Alyson one of the counsel? 11 A. That is my understanding, yes. 12 Q. So with the same firm? 13 A. I don't believe so, but I don't know. 14 MR. INSOGNA: Rosemarie, if it helps, 15 it's Alyson Lotman with Duane Morris. 16 MS. BOGDAN: Okay, I didn't see her 17 appearance on the record, so thank you. 18 BY MS. BOGDAN: 19 Q. All right. Now, what electronics are you 20 using today for this deposition? 21 A. Everything in this room. 22 Q. Okay. 23 A. A lot of electronics in this room. 24 Q. Well, the electronics that are available to 25 you personally and you can control them, I see a</p>

<p style="text-align: right;">Page 10</p> <p>1 laptop in front of you perhaps?</p> <p>2 A. Yeah, there's a laptop with a window that</p> <p>3 says "Lewis Chodosh, M.D., Marked Exhibits."</p> <p>4 Q. And are there any -- other than the exhibit</p> <p>5 portal that is on that laptop and open to you, are</p> <p>6 there any other applications or e-mails or message</p> <p>7 systems or anything available to you on that laptop?</p> <p>8 A. There are applications on there. There's</p> <p>9 nothing else open on this laptop.</p> <p>10 Q. Actually, I should --</p> <p>11 A. I think all computers have applications on</p> <p>12 them, but there's one window open on this laptop and</p> <p>13 that's the one I just told you.</p> <p>14 Q. Okay. And you're not using any of those</p> <p>15 other applications that might be available on that</p> <p>16 laptop?</p> <p>17 A. No, I am not.</p> <p>18 Q. What about any type of a cell phone or iPad</p> <p>19 or hand-held device, are you using anything like</p> <p>20 that during the deposition today?</p> <p>21 A. No.</p> <p>22 Q. What did you do to prepare for your</p> <p>23 deposition today?</p> <p>24 A. I reread some materials, including my</p> <p>25 reports. I met with attorneys, that was pretty much</p>	<p style="text-align: right;">Page 12</p> <p>1 that binder?</p> <p>2 MR. INSOGNA: Rosemarie, I think I</p> <p>3 can help with this. The binder is each of</p> <p>4 the sources cited as a footnote to</p> <p>5 Dr. Chodosh's supplemental report, it's hard</p> <p>6 copies of those documents.</p> <p>7 BY MS. BOGDAN:</p> <p>8 Q. Are there any notes or highlights that</p> <p>9 you've made on those documents that are in that</p> <p>10 binder?</p> <p>11 A. No. This binder was here, sitting at this</p> <p>12 spot when I came in this morning. It's not</p> <p>13 something that I've had; it's not something that</p> <p>14 I've looked through or made any notes on.</p> <p>15 MS. BOGDAN: The representation by</p> <p>16 Counsel is that that binder only has in it</p> <p>17 hard copies of the documents that are</p> <p>18 referenced in the doctor's supplemental</p> <p>19 report?</p> <p>20 MR. INSOGNA: That's correct.</p> <p>21 THE WITNESS: And if it helps you,</p> <p>22 there are 31 tabs in this binder.</p> <p>23 BY MS. BOGDAN:</p> <p>24 Q. And other than the documents you mentioned</p> <p>25 as well as the binder, is there anything else as you</p>
<p style="text-align: right;">Page 11</p> <p>1 it.</p> <p>2 Q. When you say you "reread materials," you are</p> <p>3 talking about the two reports that you've provided</p> <p>4 in this litigation?</p> <p>5 A. The two reports in this litigation. I</p> <p>6 looked back over the deposition from my original</p> <p>7 report. I looked over Dr. Madigan's report. Those</p> <p>8 were the primary things that I spent time with.</p> <p>9 Q. Do you have any documents with you today</p> <p>10 that you're using during this deposition?</p> <p>11 A. Yes.</p> <p>12 Q. What documents do you have?</p> <p>13 A. Do you want me to go clockwise or</p> <p>14 counterclockwise? I'll go counterclockwise.</p> <p>15 Q. Whichever you prefer, Doctor.</p> <p>16 A. I have a copy of my supplemental report, a</p> <p>17 copy of my original report, there's a binder marked</p> <p>18 "Pleadings Binder," March 10th, 2022, that has a</p> <p>19 bunch of numbers at the top of that that I'm happy</p> <p>20 to read to you if you would like.</p> <p>21 Q. What is in --</p> <p>22 A. It says it's the -- the first page, says</p> <p>23 it's "Lewis Chodosh Supplemental Expert Report</p> <p>24 Binder," and it's a tabbed set of documents.</p> <p>25 Q. Who compiled those documents that are in</p>	<p style="text-align: right;">Page 13</p> <p>1 go counterclockwise around the table?</p> <p>2 A. Yes, and I apologize, I've lost</p> <p>3 counterclockwise clockwise.</p> <p>4 So I have a copy of Dr. Madigan's report</p> <p>5 dated July 7, 2021. I have -- it's entitled</p> <p>6 "Defendant's Responses and Objections to Plaintiffs'</p> <p>7 Notice of Videotaped Deposition of Lewis Chodosh,</p> <p>8 M.D., Ph.D."</p> <p>9 I have a "Notice to Take Videotaped Oral</p> <p>10 Deposition."</p> <p>11 I have what was exhibits -- looks like one</p> <p>12 through five from the last deposition you and I did</p> <p>13 together.</p> <p>14 I have Exhibits 7 and 8 from the last</p> <p>15 deposition we did together.</p> <p>16 And then finally, there is a binder, again,</p> <p>17 that was here when I came in that says "Teva</p> <p>18 Valsartan MM and Class Cert Pleading Binder,</p> <p>19 March 10th, 2022," that appears to have two tabs.</p> <p>20 The first tab is "Plaintiffs' Consolidated Third MM</p> <p>21 Class Action Complaint" and the second tab is</p> <p>22 "Plaintiffs' Motion for Class Certification of</p> <p>23 Consumer TPP and MM Claims," and both of those are</p> <p>24 dated November 1st, 2021.</p> <p>25 MR. INSOGNA: And, Rosemarie, let me</p>

<p style="text-align: right;">Page 14</p> <p>1 just clarify one thing, when Dr. Chodosh 2 referenced the Exhibits 1 through 5 and 7 3 and 8 to the prior deposition, those are the 4 documents Bates labeled Chodosh 001 through 5 008, the calculation tables that you had 6 marked during the last deposition. 7 MS. BOGDAN: Okay. 8 BY MS. BOGDAN: 9 Q. And for that series of documents that you 10 just mentioned, Dr. Chodosh, have you made any notes 11 or highlights on any of those documents? 12 A. No, I have not. 13 Q. Now, you mentioned that you met with the 14 attorneys to prepare for this deposition. 15 How much time did you spend meeting with 16 counsel to prepare for this deposition? 17 A. It was about three hours. 18 Q. Was that all on one occasion or multiple 19 occasions? 20 A. That was one occasion. There may have been 21 a brief phone call that would have been, you know, 22 some other point over the last few days, but that 23 probably would have been less than 15 minutes. 24 MS. BOGDAN: If we could pull the 25 notice to take oral videotaped deposition</p>	<p style="text-align: right;">Page 16</p> <p>1 THE WITNESS: Great. Thank you very 2 much. 3 BY MS. BOGDAN: 4 Q. Doctor, do you -- 5 MS. BOGDAN: Has it been marked, are 6 we all set? 7 THE WITNESS: I'm not sure who you 8 are asking that question. 9 TRIAL TECHNICIAN: It has been 10 marked, yes. It has been marked as 11 Exhibit 1. 12 BY MS. BOGDAN: 13 Q. Doctor, do you recognize this notice? 14 A. Checking it. Yes, I do. 15 Q. And directing your attention to the third 16 page of the notice, Exhibit A? 17 A. Yes, I see. 18 Q. There's a document entitled "Document 19 Requests"? 20 A. Yes, I see that. 21 Q. Were you involved in assembling these 22 documents responsive to the requests in Exhibit A of 23 the notice? 24 A. Was I involved, yes. We walked through the 25 thing so that I could make sure I understood as best</p>
<p style="text-align: right;">Page 15</p> <p>1 and mark that as an exhibit, please. 2 (Document marked for identification 3 as Chodosh Deposition Exhibit No. 1.) 4 MS. BOGDAN: Is Mike there? Please 5 mark that the first exhibit. 6 TRIAL TECHNICIAN: It's on your 7 screen now. Give me one second to mark it 8 in the exhibit folder. Having a brief tech 9 glitch. 10 THE WITNESS: Should I be seeing 11 something in the folder in this window in 12 front of me? 13 TRIAL TECHNICIAN: Doctor, you should 14 have it on the screen in the conference 15 room, correct? 16 THE WITNESS: Yes, but my 17 understanding was that documents would also 18 show up in this window -- 19 TRIAL TECHNICIAN: Yes. 20 THE WITNESS: -- so that I could look 21 at them. 22 TRIAL TECHNICIAN: Yes, that's 23 correct, I'm putting them in right now. And 24 it should -- if you hit refresh you should 25 see Exhibit Number 1.</p>	<p style="text-align: right;">Page 17</p> <p>1 I could what was being requested and whether or not 2 those things existed and to a lesser extent whether 3 there were -- had been objections to any of these 4 things that you all talk about amongst yourselves 5 that I don't understand. 6 MS. BOGDAN: If you could please mark 7 the defendant's responses and objections to 8 the plaintiffs' notice as Exhibit 2, please. 9 TRIAL TECHNICIAN: The document on 10 your screen has been marked as Exhibit 2. 11 (Document marked for identification 12 as Chodosh Deposition Exhibit No. 2.) 13 BY MS. BOGDAN: 14 Q. Doctor, do you recognize this document? 15 A. I have seen it. I have not -- I have not 16 read through it. 17 Q. Okay. I'm going to ask you just a couple 18 follow-up questions with regard to the requests that 19 were made in the notice to take your deposition. 20 A. I'm sorry, are we back to the previous 21 document or the one you have me looking at now? 22 Q. Well, this one has them all repeated in it 23 so we're -- we can use the one that's up on the 24 screen now. 25 So if we -- but actually, we can take -- we</p>

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1 can take it down, I can just ask you the questions.
2 Have you done any presentations, seminars or
3 classes with regard to the risks or benefits of
4 angiotensin II receptor blockers for nitrosamines?
5 A. Are you reading Number 3?
6 Q. What I'm asking -- I'm not reading Number 3.
7 I'm asking if you have done any PowerPoints
8 or presentations or seminars regarding the risks and
9 benefits of angiotensin receptor blockers or
10 nitrosamines?
11 A. The answer to that is no, and, again, that's
12 Number 3 on the document request.
13 Q. Have you done any presentations, seminars or
14 classes with regard to medical monitoring?
15 MR. INSOGNA: Object to form.
16 THE WITNESS: Depends on how -- how
17 do you define "medical monitoring"?
18 BY MS. BOGDAN:
19 Q. The type of medical care that one would need
20 if they're at a risk of developing cancer.
21 Have you given any types of presentations or
22 seminars or classes with regard to the type of
23 medical treatment one may need if they're at a risk
24 for developing cancer?
25 A. I have not specifically given a presentation

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1 in the way that you described that. I mean, as a
2 physician and teaching medical students, for
3 example, one might talk about colonoscopy, what are
4 the guidelines for colonoscopy for screening so
5 that's -- that's monitoring. It's not a lecture
6 about colonoscopy, you know, genetic testing for
7 people who have a family history, but it would have
8 been in the general context of, you know, teaching
9 medical students, teaching graduate students, et
10 cetera, about general principles in medicine and
11 cancer biology not a dedicated presentation to, I
12 think, what you are referring to as "medical
13 monitoring."
14 Q. That answers my question. Thank you,
15 Doctor.
16 Have you authored any articles or done any
17 presentations, seminars, classes with regard to
18 hypertension treatments, ARBs or medical monitoring
19 plans?
20 A. I don't think so. It's not clear to me.
21 How is this different than the last question you
22 asked me? So articles so --
23 Q. The last question was medical monitoring.
24 I'm now asking with regard to hypertension,
25 treatments for hypertension or ARBs?

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1 A. No, I have not.
2 Q. Have you performed any research with regard
3 to angiotensin II receptor blockers?
4 A. No, I have not.
5 Q. Have you performed any research with regard
6 to nitrosamines?
7 MR. INSOGNA: Object to form, vague.
8 THE WITNESS: We -- I believe we had
9 this discussion at the last deposition. I
10 don't have articles that specifically focus
11 on the topic of nitrosamines and cancer, but
12 we have used nitrosamines in research in our
13 laboratory and I believe we talked about
14 that at length in the last deposition from
15 my original report.
16 BY MS. BOGDAN:
17 Q. We did and so my question was more geared
18 and I should have actually posed it this way, since
19 your last deposition with me have you done anything
20 new that you couldn't have testified about last time
21 because it hadn't yet occurred with regard to
22 research regarding nitrosamines?
23 A. No, I have not.
24 Q. Have you ever served as an expert for a
25 medical monitoring cause of action in another

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1 litigation?
2 A. No, I have not.
3 Q. Since your last deposition, have you done
4 any new research regarding -- or done any research
5 regarding angiotensin blockers -- angio- -- excuse
6 me -- angiotensin II receptor blockers?
7 A. No, I have not.
8 Q. Did you have a new retainer agreement or
9 letter of retention for this medical monitoring
10 cause of action that was separate and distinct from
11 the one that we spoke of at your last deposition?
12 A. To the best of my recollection, no.
13 MS. BOGDAN: If we could pull up
14 Dr. Chodosh's invoices as Exhibit 3, please.
15 (Document marked for identification
16 as Chodosh Deposition Exhibit No. 3.)
17 BY MS. BOGDAN:
18 Q. And, Dr. Chodosh, please let me know once
19 that exhibit is available to you and you are able to
20 see it.
21 A. Yes, it is, I have it.
22 Q. Can you please look through Exhibit 3 and
23 tell me if that is a complete copy of the invoices
24 that you have rendered regarding this matter?
25 A. Yes, I believe it's complete.

<p style="text-align: right;">Page 22</p> <p>1 Q. I see that the invoices stop as far as time 2 as of December 31st, 2021? 3 A. That's correct. 4 Q. Have you spent additional time since 5 December 31st, 2021? 6 A. Yes, I have. 7 Q. And you haven't yet submitted an invoice for 8 that additional time? 9 A. Correct, I have not submitted an additional 10 invoice. 11 Q. How much time have you spent working on this 12 litigation since December 31st, 2021? 13 A. Somewhere in the vicinity of about 65 or 70 14 hours. 15 Q. So the invoices that have been marked as 16 Exhibit 3 total \$336,175. 17 Does that sound right to you? 18 A. That sounds about right. 19 Q. And the 65 to 70 hours that you spent since 20 you last submitted an invoice, at what hourly rate 21 has that work been performed? 22 A. That hourly rate is \$925 an hour. 23 Q. So for an additional 65 hours at \$925 an 24 hour, that would be another \$60,125, approximately? 25 A. That sounds about right. I don't have a</p>	<p style="text-align: right;">Page 24</p> <p>1 go back, please. There we go. All right. 2 BY MS. BOGDAN: 3 Q. You see in the numbered list where it shows 4 an on-site deposition that occurred September 29th 5 and September 30th? It's about three-quarters of 6 the way down. 7 A. Yes. 8 Q. Okay. And then there are a series of 9 entries that begin on October 24th, 2021, and go 10 through December 31st, 2021? 11 A. Yes, I see that. 12 Q. Was that work that you did on the medical 13 monitoring cause of action? 14 A. And the dates, again, that you're asking 15 about are which? 16 Q. October 24th, 2021, through the end of the 17 invoice. 18 A. I actually don't recall because I also 19 recall spending time going through the deposition 20 transcripts from September 29th and September 30th 21 and I can't remember if I had to get those notarized 22 or -- so it's possible that that's what the October 23 dates are. I don't -- I don't specifically recall. 24 Q. Do you have any written record of your 25 activities done in this matter that has more of a</p>
<p style="text-align: right;">Page 23</p> <p>1 calculator in front of me so I don't know. 2 Q. And on the third page of this exhibit -- 3 A. Yes -- oh, third page, sorry. 4 Q. -- third page, which I believe would be with 5 the date January 18th, 2022, at the top? 6 A. That's not my third page. My third page is 7 parking receipts from January 28th, 2022. 8 Q. Okay. How about -- it's probably then your 9 first page. 10 A. What's up on the screen is the one I was 11 just referring to, which is parking receipts. 12 MS. BOGDAN: That's correct. 13 If the tech could please move to the 14 first page of this exhibit, which would be, 15 I believe, with a date -- okay. 16 BY MS. BOGDAN: 17 Q. So you have a different -- here's the first 18 page, which is August 3rd, and the third page of 19 this exhibit should have a date of January 18th at 20 the top? 21 A. That's the fifth page of my exhibit. 22 Q. Okay. 23 MS. BOGDAN: If the tech could please 24 move to the page that begins with 25 January 18th. There we go. Perfect. Oh,</p>	<p style="text-align: right;">Page 25</p> <p>1 description of what you did, other than what's on 2 the invoice? 3 A. No. I could probably figure it out by 4 looking at when the errata for the deposition 5 transcripts were notarized, that would probably give 6 me a clue, but there are no other notes that would 7 give me more information on it. 8 Q. Did you go about recording your time in this 9 invoice in the same -- or for -- in the same manner 10 that you used as you testified to in your prior 11 deposition? 12 MR. INSOGNA: Object to form. 13 THE WITNESS: Yeah, well, no. I 14 mean, I clarified how I did it in the prior 15 deposition since the prior invoice was for a 16 very short period of time, about five weeks. 17 So for things like this that's spread 18 over months, I would typically just put a 19 date and a number for hours spent. 20 BY MS. BOGDAN: 21 Q. And that's what's recorded on the invoice? 22 A. That's what's recorded on the invoice after 23 I fill-in the other things, like the review of 24 medical and scientific materials and making sure 25 that the year is on there and things like that.</p>

<p style="text-align: right;">Page 26</p> <p>1 Q. Is there any written record that would 2 provide more detail as to what medical and 3 scientific literature you reviewed on any particular 4 date? 5 A. No, there is not. 6 MS. BOGDAN: If you could please pull 7 up Dr. Chodosh's supplemental report. And I 8 believe we're on Exhibit 4. 9 THE WITNESS: I don't -- yes. 10 (Document marked for identification 11 as Chodosh Deposition Exhibit No. 4.) 12 BY MS. BOGDAN: 13 Q. Do you recognize that document that's been 14 marked as Exhibit 4? 15 A. Yes, I do. 16 Q. What is that document? 17 A. That is my supplemental report and looks 18 like the appended materials and the exhibits. 19 MS. BOGDAN: If we could please pull 20 up the amended list of materials considered, 21 which is number 5. I think it's entitled 22 "List of Materials Considered." 23 THE WITNESS: Yeah. I can see it on 24 the computer. I don't see it on the screen. 25 MS. BOGDAN: I don't see it on the</p>	<p style="text-align: right;">Page 28</p> <p>1 BY MS. BOGDAN: 2 Q. That's correct. I'm asking if there are any 3 additional materials considered that have been added 4 to this list that were not in the list that we spoke 5 about at your last deposition, that accompanied your 6 first report? 7 A. So there would have been reports from, you 8 know, experts, the -- reports from experts in this 9 matter, in the medical monitoring matter, so 10 obviously I wouldn't have had those back in August. 11 I don't believe there's the -- any differences in 12 scientific materials, you know, publications, things 13 like that, but I would have to go through it line by 14 line to tell you that there isn't anything. 15 Just sitting here today, I don't recall 16 anything that was added. Any other publications 17 that were added, to clarify. 18 Q. Did you review any additional internal 19 documents of the defendants between your last 20 deposition and today? 21 A. Not to the best of my recollection, no. 22 Q. Now, your hourly rate for your continued 23 work on this litigation is \$925 per hour? 24 A. That's correct. 25 Q. And your original rate for your work when</p>
<p style="text-align: right;">Page 27</p> <p>1 screen yet either, Dr. Chodosh. There we 2 go. 3 (Document marked for identification 4 as Chodosh Deposition Exhibit No. 5.) 5 BY MS. BOGDAN: 6 Q. As the document that's been marked 7 Exhibit 5, is that your amended list of materials 8 considered that accompanied your supplemental expert 9 report? 10 A. Yes. 11 Q. And is that a comprehensive list of the 12 materials that you considered? 13 A. Yes, it is. 14 Q. Were there additional materials added to 15 this list that you considered for your supplemental 16 report that were not on the list of materials 17 considered for your original report? 18 MR. INSOGNA: Object to form. 19 THE WITNESS: You're asking me if 20 there are any things in the thing up on the 21 screen, the amended list of materials 22 considered from March 8, you're asking me is 23 there anything on here that wasn't in the 24 original list of materials considered back 25 in whenever that was, August 2021?</p>	<p style="text-align: right;">Page 29</p> <p>1 you were first retained on this litigation was 850 2 per hour; isn't that correct? 3 A. That's correct. Yes, that's correct. 4 Q. When did your hourly rate change? 5 A. January 1st. 6 Q. What percentage of your income comes from 7 litigation work? 8 MR. INSOGNA: Object to form. 9 THE WITNESS: I can't tell you a 10 precise number and for sure it would vary 11 over the years. 12 BY MS. BOGDAN: 13 Q. Can you give me a range? 14 A. Over the years, it would vary from zero or 15 1% to something probably less than half of what I 16 earned in my roles at the University of 17 Pennsylvania, but I can't -- I can't give you any -- 18 any numbers. I've never calculated that. 19 Q. So it depends on -- it varies year to year; 20 is that a fair statement? 21 A. Yes. 22 Q. What question were you asked to answer with 23 regard to your supplemental report? 24 A. As it states on the first page of my 25 supplemental report, I have been asked to "Provide</p>

<p style="text-align: right;">Page 30</p> <p>1 my opinions regarding the scientific and medical 2 basis for the requests for medical monitoring for 3 cancer, as expressed in Plaintiffs' Third Amended 4 Medical Monitoring Class Action Complaint filed 5 November 1st, 2021." 6 Q. Does that statement encompass all that you 7 were asked to do with regard to rendering the 8 opinion that's in your supplemental report? 9 MR. INSOGNA: Objection to form. 10 THE WITNESS: I think that statement 11 adequately covers it to my understanding of 12 it. 13 BY MS. BOGDAN: 14 Q. Now, you reviewed Dr. Dipak Panigraphy's 15 report? 16 A. If you're asking me did I review 17 Dr. Panigraphy's report as he originally filed it 18 back in the summer or whenever that was of 2021, the 19 answer is yes, and my understanding is that it was 20 more or less exactly that same report that was 21 refiled in this medical monitoring matter. 22 Q. And did you review the whole report or just 23 parts of the report? 24 A. I don't recall. 25 Q. Did you review Dr. Panigraphy's deposition</p>	<p style="text-align: right;">Page 32</p> <p>1 A. So that title is familiar, but the titles 2 that are listed in this binder -- so this says 3 "Third Amended Medical Monitoring Class Action 4 Complaint" -- 5 Q. Did you -- 6 A. [Zoom technical malfunction.] 7 Q. It's a different document, but did you 8 review that document the one you just read, the 9 third amended medical monitoring class action 10 complaint? 11 A. Yes, I did and the other, as I said 12 previously, was the plaintiffs' motion for class 13 certification of consumer third-party payor and 14 medical monitoring claims. 15 Q. You read that document? 16 A. Yes, I did. And this is assuming we're not 17 referring to different things or -- yeah. I mean, 18 the titles were -- 19 Q. That's fine, Doctor, you -- 20 [cross-talking] 21 A. I don't think this is the one. 22 Q. When you say you don't think it is the one, 23 are you looking at a document that you don't think 24 you reviewed? 25 A. If it's what's in Tab 2, it actually looks</p>
<p style="text-align: right;">Page 31</p> <p>1 testimony? 2 A. I believe that I read his -- I believe his 3 first deposition. Again, I don't know what the date 4 was from his original report. I don't believe -- I 5 think he was -- there was an additional session that 6 I don't believe I reviewed, but I'm not sure. 7 Q. Did you review Dr. Madigan's expert report? 8 A. Yes, I did. And by which you mean 9 Dr. Madigan's report for the medical monitoring of 10 the -- yeah, the one that I have -- let's see. 11 Q. You can tell me the date of the report, that 12 will -- 13 A. First page for the hard copy I have says 14 "July 7th, 2021." 15 Q. Did you review Dr. Madigan's deposition 16 testimony? 17 A. I'm not -- I don't recall. I'm not sure 18 that I did. 19 Q. Did you review the plaintiffs' memorandum of 20 law in support of the medical monitoring motion for 21 class certification? 22 A. Can you repeat what the title of that was? 23 Q. Plaintiffs' memorandum of law in support of 24 the medical monitoring plaintiffs' motion for class 25 certification?</p>	<p style="text-align: right;">Page 33</p> <p>1 to be something different. This looks like it's 2 economic. 3 Can you -- 4 MR. INSOGNA: Yeah. 5 MS. BOGDAN: My question -- 6 MR. INSOGNA: Yeah, for the record, I 7 think that the hard copy we printed out for 8 Dr. Chodosh this morning may be the wrong 9 document. As he said, he has a different 10 thing in front of him than what is listed on 11 the amended list of -- the list of materials 12 considered. 13 THE WITNESS: So if it helps, just 14 looking at the titles that I put in my 15 report, it was the third amended medical 16 monitoring class action complaint and there 17 was the memorandum of law in support of 18 plaintiffs' motion for class certification. 19 Does that answer your question? 20 Those were the two primary documents that I 21 was reviewing for attorney-generated things. 22 BY MS. BOGDAN: 23 Q. And other than those two attorney-generated 24 documents, did you review for purposes of your 25 report any other attorney-generated documents, and</p>

<p style="text-align: right;">Page 34</p> <p>1 I'm adopting your terminology, or were those the two 2 that you've referenced in your report and you 3 considered when drafting it? 4 A. Those were the two that -- those were the 5 two that I recall. It's possible I was given a 6 document that had things related to economics that 7 I -- if I had opened that, I would not have read 8 through that. 9 Q. Was it important for you to understand 10 Dr. Madigan's opinions in order to provide a medical 11 monitoring opinion in this case? 12 A. Yes, it was. 13 Q. Was it important for you to understand 14 Dr. Panigraphy's opinions in order to provide an 15 opinion in this case? 16 A. Yes. 17 Q. Do you have any experience in actually 18 setting up a medical monitoring program for a cohort 19 of people who are at risk for developing cancer? 20 A. No, I do not. 21 Q. Did you review the medical monitoring plan 22 offered by the plaintiffs in this litigation? 23 A. What I reviewed was what I assume is the 24 reference to that in Dr. Madigan's report. 25 Q. Directing your attention to paragraph 6 of</p>	<p style="text-align: right;">Page 36</p> <p>1 from? 2 A. The language "require additional targeted 3 testing," which is what's quoted, is that what 4 you're referring to? 5 Q. That language and then the description that 6 you have of what that additional targeted testing 7 would be, did you get that from the memorandum of 8 law in support of plaintiffs' motion for class 9 certification? 10 A. I need to look at that material to answer 11 your question. 12 THE WITNESS: So is this the one that 13 I have or is this the one that I don't have, 14 the memorandum of law in support of motion 15 for class certification? 16 MR. INSOGNA: I don't think we have a 17 hard copy in the room. 18 THE WITNESS: Okay. Well, I'm going 19 to need to look at that to know the answer 20 to your question. 21 BY MS. BOGDAN: 22 Q. Okay. Did you cite anything other than the 23 memorandum of law in support of plaintiffs' motion 24 for class certification in that paragraph? 25 A. No, I did not.</p>
<p style="text-align: right;">Page 35</p> <p>1 your report, which is marked I believe -- I believe 2 we marked it four? 3 A. Yes. 4 Q. And can you see that now, Doctor? It just 5 popped up on my screen. 6 A. Yes, I can. 7 Q. And referring you to that part of your 8 paragraph that begins "And that such Plaintiffs 9 "require additional targeted testing" consisting of 10 periodic fecal occult blood testing, low dose CT 11 chest scan, urinalysis, blood smear evaluation, 12 colonoscopy and upper endoscopy and Galleri 13 multi-cancer early detection blood test or similar 14 liquid biopsy." 15 Do you see that? 16 A. I see those words, yes. 17 Q. Did you review the medical monitoring plan 18 that had been submitted by Dr. Kaplan as part of 19 your review in this case? 20 A. I may or may not have glanced at it. I 21 would not have reviewed it in detail. 22 Q. And the language that you have there in 23 paragraph 6, you're citing to the memorandum of law 24 in support of plaintiffs' motion for class 25 certification as to where you got that language</p>	<p style="text-align: right;">Page 37</p> <p>1 Q. Do you recognize that type of additional 2 testing as a physician? 3 MR. INSOGNA: Objection, vague. 4 THE WITNESS: Are you speaking to the 5 portion that begins "Periodic fecal occult 6 blood screening"? 7 BY MS. BOGDAN: 8 Q. Yes, I am. I am referring to the part that 9 begins with "Periodic fecal occult blood testing, 10 low dose CT chest scan, urinalysis, blood smear 11 evaluation, colonoscopy and upper endoscopy and 12 Galleri," if that's how you pronounce it, 13 "multi-cancer early detection blood test or similar 14 liquid biopsy." 15 Do you recognize those types of tests? 16 A. I recognize all of those types of tests, 17 including the liquid biopsy, as vague as that term 18 is, but not -- I'm not familiar with the Galleri -- 19 in any detail, of the Galleri multi-cancer early 20 detection blood test. I can infer based on a -- or 21 similar liquid biopsy that it is a liquid biopsy 22 based method, meaning a blood-based method. 23 Q. Are you offering any opinions here today 24 whether or not those additional tests that are 25 listed in paragraph 6 of your report are appropriate</p>

<p style="text-align: right;">Page 38</p> <p>1 tests for someone who is at risk of developing 2 cancers? 3 MR. INSOGNA: Object to form. 4 THE WITNESS: Could you repeat the 5 question, please? 6 BY MS. BOGDAN: 7 Q. Are you offering any opinion with regard to 8 those specific tests and whether or not they're 9 appropriate tests for someone who is at risk of 10 developing cancers? 11 MR. INSOGNA: Objection, vague. 12 THE WITNESS: If what you're asking 13 me is, was I asked to opine on the 14 appropriateness of those specific tests for 15 this portion of the litigation, no, that's 16 not what I'm offering opinions on, however, 17 I'm a physician so, of course, I would have 18 opinions about those things when asked as a 19 physician. 20 But I was not asked to specifically 21 address those tests and their 22 appropriateness in this litigation, again, 23 other than that is informed by me being a 24 physician. 25 BY MS. BOGDAN:</p>	<p style="text-align: right;">Page 40</p> <p>1 But as a physician, if asked as a 2 physician, I can't remove that part of my 3 brain. 4 BY MS. BOGDAN: 5 Q. I understand your response, Doctor, but what 6 I'm asking is, are you going to as an expert in this 7 litigation offer opinions in those areas? 8 MR. INSOGNA: Objection, vague. 9 BY MS. BOGDAN: 10 Q. Personally, as a physician, if I asked you 11 the questions, but are you offering those opinions 12 in your role as an expert in this litigation? 13 MR. INSOGNA: Objection, vague as to 14 "those opinions." 15 THE WITNESS: I'm sorry that we're 16 going around here. 17 My understanding is that there are 18 other experts involved who are addressing 19 the issues of those specific tests. I can't 20 tell you sitting here now what questions you 21 or some other attorney will ask me in court 22 in my role as a physician. 23 BY MS. BOGDAN: 24 Q. With regard to the first item of additional 25 testing that you list in paragraph 6, "fecal occult</p>
<p style="text-align: right;">Page 39</p> <p>1 Q. And did you not review the report of 2 plaintiffs' expert Edward Kaplan, which set forth 3 the plaintiffs' proposed medical monitoring plan? 4 MR. INSOGNA: Objection, misstates 5 testimony. 6 THE WITNESS: I believe what I said 7 was that I may have glanced at it, I may 8 have skimmed it, but I did not read it in 9 great detail. I don't recall sitting here 10 today. 11 BY MS. BOGDAN: 12 Q. Is -- and just so I'm clear, when you say 13 you were not asked to offer an opinion on the 14 appropriateness of various tests for someone who is 15 at risk of developing cancer, is it my -- is my 16 understanding correct, that you're not going to be 17 offering opinions in this litigation with regard to 18 that issue? 19 MR. INSOGNA: Objection, vague. 20 THE WITNESS: I mean, I think the way 21 I answered it, your last question is 22 accurate and that's my best answer. I was 23 not asked to specifically address those 24 things, nor do I believe they're 25 specifically addressed in my report.</p>	<p style="text-align: right;">Page 41</p> <p>1 blood testing," is that an appropriate test to give 2 a patient who is at risk for developing a certain 3 type of cancer? 4 MR. INSOGNA: Objection, vague. 5 THE WITNESS: Yeah, so you're now -- 6 you're now asking me questions about -- in a 7 medical practice when might one ask a 8 patient to do fecal occult blood testing and 9 I think what I'm trying to explain to you 10 is, I'm not offering opinions on those 11 things, nor would they -- nor were they 12 covered in my report. 13 If somebody asked me as a physician 14 have I ever asked a patient to do that, 15 well, I can answer that, but I'm not 16 offering opinions about, oh, you know, what 17 are the test characteristics of fecal occult 18 blood testing in different populations in 19 the United States. Those aren't my 20 opinions. This is not -- it's not in my 21 report. 22 BY MS. BOGDAN: 23 Q. The same question, then, I would ask with 24 regard to -- I'm assuming that should be "low dose 25 CT chest scan" --</p>

<p style="text-align: right;">Page 42</p> <p>1 A. Yes, it is.</p> <p>2 Q. -- the next item?</p> <p>3 A. Yes.</p> <p>4 Q. Are you offering any opinions with regard to</p> <p>5 the appropriateness of low dose CT chest scans?</p> <p>6 MR. INSOGNA: Objection, vague.</p> <p>7 THE WITNESS: So -- so my</p> <p>8 understanding is the opinions that I am</p> <p>9 being asked, that I was asked to give and</p> <p>10 that I will be asked about in court, to the</p> <p>11 best of my understanding, are the things</p> <p>12 that are in my supplemental report.</p> <p>13 And that if I am asked questions as a</p> <p>14 physician about any of this list of tests,</p> <p>15 well, I can answer in my role as a</p> <p>16 physician, if I was asked about that by you</p> <p>17 or someone else, but that was not the focus</p> <p>18 of my report, nor, I believe, is there a</p> <p>19 discussion of those particular tests in my</p> <p>20 supplemental report.</p> <p>21 BY MS. BOGDAN:</p> <p>22 Q. And likewise, there is no discussion of the</p> <p>23 appropriateness of your analysis, blood smear</p> <p>24 evaluation, colonoscopy and upper endoscopy and</p> <p>25 Galleri multi-cancer early detection blood test or</p>	<p style="text-align: right;">Page 44</p> <p>1 program?</p> <p>2 MR. INSOGNA: So my objection is</p> <p>3 still to the question, vague.</p> <p>4 But you can answer that question.</p> <p>5 THE WITNESS: I -- yeah, my</p> <p>6 apologies, but I feel like I've answered</p> <p>7 this in the best way that I can a couple</p> <p>8 times already, so I'm not -- I'm not sure</p> <p>9 what else I can say that will -- that will</p> <p>10 clarify this.</p> <p>11 I was not asked by defense attorneys</p> <p>12 to offer opinions, that is, to evaluate and</p> <p>13 write opinions in my report about whether</p> <p>14 the tests you are referring to here that</p> <p>15 were proposed for plaintiffs in this</p> <p>16 litigation. I was not asked to evaluate</p> <p>17 whether those tests, those specific tests</p> <p>18 would be appropriate for -- for specific</p> <p>19 plaintiffs.</p> <p>20 What I'm trying to express is that as</p> <p>21 a physician, knowing what those tests are,</p> <p>22 if asked as a physician, I have opinions</p> <p>23 about that insofar as I'm a physician. I</p> <p>24 don't know what questions that you're going</p> <p>25 to ask me in court, but it's not in my --</p>
<p style="text-align: right;">Page 43</p> <p>1 similar liquid biopsies in your report, correct?</p> <p>2 MR. INSOGNA: Objection, vague.</p> <p>3 Rosemarie, I don't want to step on</p> <p>4 your questions and all. I think -- I think</p> <p>5 we're having difficulty with the "at risk of</p> <p>6 cancer" language as opposed to plaintiff</p> <p>7 specifically.</p> <p>8 MS. BOGDAN: Excuse me? You broke up</p> <p>9 a little bit. You said --</p> <p>10 MR. INSOGNA: I'm trying to</p> <p>11 avoid anything that's going to --</p> <p>12 MS. BOGDAN: Yeah, I mean --</p> <p>13 MR. INSOGNA: -- Dr. Chodosh while</p> <p>14 there's a question pending. I think I see</p> <p>15 where the disconnect is in the questioning</p> <p>16 and it's your phrase "people at risk of</p> <p>17 cancer."</p> <p>18 BY MS. BOGDAN:</p> <p>19 Q. All right. But my question -- my question</p> <p>20 stands.</p> <p>21 A. I don't know how else to answer your</p> <p>22 question.</p> <p>23 Q. I mean, is the doctor offering opinions with</p> <p>24 regard to the particular targeted testing that the</p> <p>25 plaintiffs have provided in the medical monitoring</p>	<p style="text-align: right;">Page 45</p> <p>1 it's not in my supplemental report.</p> <p>2 There is no discussion of those</p> <p>3 individual tests in my supplemental report.</p> <p>4 BY MS. BOGDAN:</p> <p>5 Q. But since you've indicated to me now, I</p> <p>6 think, multiple times that you do have opinions as a</p> <p>7 physician and if someone asked you, you would</p> <p>8 comment on your knowledge and evaluation of whether</p> <p>9 those tests would be appropriate tests because you</p> <p>10 have stated that as a physician you have opinions on</p> <p>11 those and if you're asked, you would provide them,</p> <p>12 then, I am going to ask as a physician what those</p> <p>13 opinions are.</p> <p>14 A. Okay.</p> <p>15 Q. Okay. So with regard to the additional</p> <p>16 targeted testing consisting of periodic fecal occult</p> <p>17 blood testing, are you familiar with that test?</p> <p>18 A. Yes, I am.</p> <p>19 Q. And is that test used in cancer detection?</p> <p>20 A. It can be, yes.</p> <p>21 Q. With regard to low dose CT chest scans, are</p> <p>22 you familiar with that test?</p> <p>23 A. Yes, I am.</p> <p>24 Q. Would that test be used in cancer detection?</p> <p>25 A. That test, as I understand it, can be used</p>

<p style="text-align: right;">Page 46</p> <p>1 in cancer screening.</p> <p>2 Q. With regard to urinalysis, are you familiar,</p> <p>3 with that test?</p> <p>4 A. Yes, I am.</p> <p>5 Q. Would that test be used in cancer screening?</p> <p>6 A. For cancer screening, not commonly.</p> <p>7 Q. For cancer diagnosis?</p> <p>8 A. As the word is written, "urinalysis," and as</p> <p>9 the way that I am used to referring to that word, in</p> <p>10 the clinic and in the hospital a urinalysis is not</p> <p>11 the test that would typically be ordered to detect</p> <p>12 cancer.</p> <p>13 Q. With regard to blood -- blood smear</p> <p>14 evaluation -- there was a lot of feedback there so I</p> <p>15 will repeat my question.</p> <p>16 With regard to blood smear evaluation, are</p> <p>17 you familiar with that test?</p> <p>18 A. Yes, I am.</p> <p>19 Q. Is that test used for cancer screening or</p> <p>20 diagnosis?</p> <p>21 A. It is a test that could be used potentially</p> <p>22 to detect cancer.</p> <p>23 Q. With regard to colonoscopy and upper</p> <p>24 endoscopy, are you familiar with those tests?</p> <p>25 A. Yes, I am.</p>	<p style="text-align: right;">Page 48</p> <p>1 paragraph and then it's a fine time to take</p> <p>2 a break.</p> <p>3 BY MS. BOGDAN:</p> <p>4 Q. About the use of similar, you know, liquid</p> <p>5 biopsies or detection blood tests for cancer</p> <p>6 screening, are you familiar with their use for</p> <p>7 cancer screening?</p> <p>8 A. I heard you say "liquid biopsy," but you</p> <p>9 also said something else about blood tests, you were</p> <p>10 breaking up.</p> <p>11 So are you referring to two things or to one</p> <p>12 thing?</p> <p>13 Q. The audio is a little broken, Dr. Chodosh,</p> <p>14 and I'm even hearing myself in bits and pieces so</p> <p>15 let me reask the question.</p> <p>16 Are you familiar with liquid biopsies or</p> <p>17 detection blood tests used as cancer screening</p> <p>18 tests?</p> <p>19 A. In your -- my understanding is based on this</p> <p>20 paragraph, you're using "detection blood test" not</p> <p>21 to refer to a blood smear, but as it is written for</p> <p>22 the Galleri multi-cancer early detection blood test</p> <p>23 or similar liquid biopsy.</p> <p>24 Q. That's correct.</p> <p>25 A. So I am -- as I said, I am familiar with</p>
<p style="text-align: right;">Page 47</p> <p>1 Q. Can those tests be used to screen or</p> <p>2 diagnose cancer?</p> <p>3 A. That is one of the purposes to which those</p> <p>4 tests can be used.</p> <p>5 Q. And with regard to liquid biopsy detection</p> <p>6 blood tests, are you familiar with those types of</p> <p>7 tests?</p> <p>8 A. I am familiar with those types of tests but</p> <p>9 as you can imagine, the term "liquid biopsy," is</p> <p>10 almost a colloquial term. It's a vague term, that</p> <p>11 doesn't specify a particular test, but I believe</p> <p>12 from context, I understand what that is and so your</p> <p>13 question about that is -- could you repeat that?</p> <p>14 Q. My question is could that type of test be</p> <p>15 used to screen or diagnose cancer?</p> <p>16 A. To my understanding, that would only be in</p> <p>17 experimental use, presumably for research purposes.</p> <p>18 I am not aware of that test being used in a standard</p> <p>19 of care practice for the detection of cancer but,</p> <p>20 again, it's a colloquial and vague term, so...</p> <p>21 MR. INSOGNA: Rosemarie, we've been</p> <p>22 going for about an hour since we started, is</p> <p>23 now an okay time for a comfort break?</p> <p>24 MS. BOGDAN: Let me just ask just a</p> <p>25 follow-up question with regard to this</p>	<p style="text-align: right;">Page 49</p> <p>1 liquid biopsy and what types of tests that generally</p> <p>2 refers to. I'm not specifically familiar with the</p> <p>3 Galleri version of that test and I'm just -- I'm</p> <p>4 reading based on context that that test is a similar</p> <p>5 liquid biopsy.</p> <p>6 Q. Are they used for cancer screening or cancer</p> <p>7 diagnosis or both?</p> <p>8 A. So as I said, this is not, to my</p> <p>9 understanding, for the detection of cancer or</p> <p>10 screening. This would not be standard of care. My</p> <p>11 understanding is to the extent that these would be</p> <p>12 used, it would be in an experimental setting for</p> <p>13 research purposes.</p> <p>14 MS. BOGDAN: Okay. Do you want to --</p> <p>15 I think someone asked for a break. I can't</p> <p>16 see who, but I'm assuming it was probably</p> <p>17 Nick.</p> <p>18 MR. INSOGNA: Yes, it was, if we</p> <p>19 could, just five minutes, that would be</p> <p>20 great. Thank you.</p> <p>21 THE VIDEOGRAPHER: Off the record</p> <p>22 10:24.</p> <p>23 (Brief recess.)</p> <p>24 THE VIDEOGRAPHER: We are back on the</p> <p>25 record at 10:33 a.m.</p>

<p style="text-align: right;">Page 50</p> <p>1 MS. BOGDAN: Is Nick ready? I don't 2 see him. 3 MR. INSOGNA: I am. 4 MS. BOGDAN: Okay. 5 MR. INSOGNA: I'm sorry. 6 MS. BOGDAN: Okay. Okay. That's 7 okay. I didn't want to be accused of 8 starting without counsel ready so there we 9 are. All right. 10 BY MS. BOGDAN: 11 Q. Now, Dr. Chodosh, directing you to page 4 of 12 your report, which I believe you have a paper copy 13 of there, right? 14 A. Yes. 15 Q. You have a section title of your report that 16 reads "Plaintiffs proposed approach cannot ascertain 17 actual NDMA or NDEA exposures"? 18 A. That's correct. 19 MS. BOGDAN: You can take down that 20 exhibit. 21 BY MS. BOGDAN: 22 Q. Now, you considered FDA test results of 23 NDMA-contaminated valsartan when researching and 24 investigating this case, correct? 25 A. Can you restate the question?</p>	<p style="text-align: right;">Page 52</p> <p>1 discussing with their patient some type of screening 2 or whether you're talking about medical monitoring 3 programs that have been set up in litigation or for 4 some other purposes. 5 Q. Referring to the latter, which would be a 6 medical monitoring program that's been set up for a 7 litigation or for another matter, which could be a 8 cohort that was exposed, for example, to a 9 carcinogen, an actual program, not an individual 10 patient/doctor decision as to how to monitor a 11 particular patient? 12 A. So based on your question, not for the 13 purposes of litigation but you appended something to 14 that that was like "and other things." I don't know 15 what you are referring to. 16 Q. Meaning, are you familiar with a medical 17 monitoring program that may not be related to 18 litigation, but is a program that is available for 19 any person that might meet the criteria for that 20 cohort to participate in because they were exposed 21 to something environmentally or -- you know, I'm 22 just trying to understand your familiarity with 23 medical monitoring programs. 24 I'm not asking about an individual decision 25 between a doctor and a patient as to a program for</p>
<p style="text-align: right;">Page 51</p> <p>1 Q. Did you, as part of your review of this 2 matter look at the laboratory analysis of valsartan 3 products done by the FDA? 4 A. Yes, I did. 5 Q. Now, is your claim that plaintiffs cannot 6 ascertain actual NDMA or NDEA exposures one of the 7 basis for your opinions that you're rendering? 8 MR. INSOGNA: Object to form. 9 THE WITNESS: That is -- that is one 10 of my critiques of the proposal that has 11 been made, yes. 12 BY MS. BOGDAN: 13 Q. Are you aware of approved medical monitoring 14 programs that have potentially varying levels of 15 individual exposures? 16 A. I'm not sure what you are referring to. 17 Q. Are you familiar with any approved medical 18 monitoring programs for other litigations? 19 A. For other litigations, no. 20 Q. Are you aware of approved medical monitoring 21 programs for any cohort of people that were exposed 22 to a carcinogen? 23 A. When you say "medical monitoring programs," 24 I'm not sure if what you're referring to is what a 25 physician might prescribe for a patient after</p>	<p style="text-align: right;">Page 53</p> <p>1 an individual. I'm asking about medical monitoring 2 programs that are available to a group. 3 A. Well, maybe I can help clarify this by 4 saying -- by giving you an example. So if there's a 5 patient of a certain age with, you know, 150 pack a 6 year smoking history, that would meet certain 7 guidelines for doing low dose chest CT for 8 screening, but that's -- to my understanding, we're 9 not talking about physicians and patients, not what 10 I think you are referring to by "and other things." 11 Is that -- do I have -- am I understanding 12 you correctly? 13 Q. You are understanding me correctly. 14 I'm asking about your familiarity with 15 established programs that if an individual meets the 16 criteria they can participate in a set program, as 17 opposed to an individual screening decided upon by a 18 doctor and their patient? 19 A. So there are certainly research protocols, 20 for instance, the research trials that went into the 21 low dose chest CT scanning and screening for lung 22 cancer. Again, I don't think that's what you're 23 referring to. Maybe if you could give me an example 24 of what you're referring to, that might make it 25 clearer for me. I just -- I don't know what you</p>

<p style="text-align: right;">Page 54</p> <p>1 mean by "program." 2 Q. For example, if there is a group of 3 individuals that were working in a sick building, 4 for example, and were exposed in that building and 5 that the state or the government has set up a 6 screening program, but it's a medical monitoring 7 program for anyone that worked in that building for 8 more than X number of years. 9 Are you familiar with any established 10 medical monitoring programs of that nature? 11 A. Based on your example and your explanation, 12 no, I don't believe so. 13 Q. When there are potential varying levels of 14 exposure can't averages and means and medians and 15 midpoints and ranges be used to assess varying 16 levels? 17 MR. INSOGNA: Objection, vague. 18 THE WITNESS: That's such a -- that's 19 such a general question, I can't even begin 20 to answer it. If you would like to give me 21 an example, I would be happy to comment on 22 it, but I can't answer that question based 23 on the way you phrased it. 24 BY MS. BOGDAN: 25 Q. Okay. If you have a group of people that</p>	<p style="text-align: right;">Page 56</p> <p>1 A. All right. 2 Q. Your supplemental expert report, you don't 3 mention the possibility that plaintiffs can 4 ascertain NDMA or NDEA exposures by using averages 5 or means or medians or midpoints or ranges of 6 exposure, correct? 7 A. I do not recall any discussion in materials 8 that I've read of plaintiffs proposing that and if 9 you could point me to the section where they do 10 that, it might jog my memory, but I don't recall it. 11 Q. I'm asking if you mentioned it in your 12 report? 13 A. If I mentioned what in my report? 14 Q. The possibility that plaintiffs could 15 utilize means, averages, medians or ranges to 16 estimate exposure to NDMA or NDEA in 17 valsartan-containing drugs? 18 A. What I'm trying to say is that my report 19 comments on what plaintiffs did say and what 20 plaintiffs did propose, as I understood it. 21 And I'm telling you, again, I do not recall 22 any point in Dr. Madigan's report or the two 23 documents with names longer than I care to repeat, 24 the amended motion and whatever the other one was, I 25 do not recall any proposal by plaintiffs to use</p>
<p style="text-align: right;">Page 55</p> <p>1 had varying levels of exposure to a carcinogen 2 because they worked in a plant, isn't it possible to 3 use means or medians or averages to determine the 4 levels of exposure? 5 MR. INSOGNA: Same objection. 6 THE WITNESS: Maybe you could give me 7 an example of a carcinogen and a plant. 8 It's just such a general question, I 9 can't -- I don't have enough information to 10 answer you. 11 BY MS. BOGDAN: 12 Q. We'll come back to it actually. I'll just 13 move on at this point. 14 With regard to this particular matter, in 15 your expert report you don't mention the possibility 16 that plaintiffs may have utilized means, medians, 17 midpoints or ranges to estimate plaintiffs' exposure 18 to NDMA in contaminated valsartan-containing drugs, 19 correct? 20 A. Could you restate that? I could not follow 21 that question. 22 Q. I'm asking if in your expert report -- 23 A. You're talking about my original report or 24 the supplemental report? 25 Q. The supplemental report first, all right?</p>	<p style="text-align: right;">Page 57</p> <p>1 midpoints or averages or things like that. 2 If you could point me to that language, it 3 might jog my memory, but I do not recall it. 4 Can you point me to the language? 5 Q. I'm not asking you if plaintiffs proposed 6 it. 7 I'm asking if you commented or considered it 8 in your supplemental report the fact that plaintiffs 9 could rely on means, medians, midpoints or ranges to 10 estimate exposure? 11 A. If you're asking me in writing my 12 supplemental report, did imagine or consider the 13 universe of possibilities of things that plaintiffs 14 might have proposed but did not, I did not consider 15 the universe of possibilities of things that they 16 might have said or might have proposed but didn't. 17 I was focused on what they did say and what they did 18 propose. 19 Q. In your expert report, did you attempt to 20 assess the average or median or midpoint or ranges 21 of NDMA or NDEA associated for each NDC code? 22 MR. INSOGNA: Objection, vague. 23 THE WITNESS: I apologize, that 24 was -- that was a very long question and I 25 followed you right until the end about the</p>

<p style="text-align: right;">Page 58</p> <p>1 NDC code.</p> <p>2 BY MS. BOGDAN:</p> <p>3 Q. In your expert report, did you attempt to</p> <p>4 assess the means, averages, midpoints or range of</p> <p>5 NDMA or NDEA exposure associated for each NDC code</p> <p>6 of valsartan-containing drugs that had</p> <p>7 contamination?</p> <p>8 MR. INSOGNA: Objection to form.</p> <p>9 THE WITNESS: And by "expert report,"</p> <p>10 again, I'm not sure if you're talking about</p> <p>11 the supplemental report or my original</p> <p>12 report, but what I -- what I did was</p> <p>13 estimate the range, which is what was the</p> <p>14 maximum hypothetical exposure based on when</p> <p>15 products from particular manufacturers were</p> <p>16 on the US market, recognizing -- and that</p> <p>17 was -- we talked for a very long time at my</p> <p>18 last deposition about those calculations.</p> <p>19 Those were the maximum possible</p> <p>20 hypothetical exposures based on FDA</p> <p>21 measurements where the minimum would have</p> <p>22 been things that were below the FDA ADI of</p> <p>23 96 nanograms per day so that -- that is that</p> <p>24 range, irrespective of any NDC codes.</p> <p>25 BY MS. BOGDAN:</p>	<p style="text-align: right;">Page 60</p> <p>1 determine a specific exposure.</p> <p>2 And that is why the calculations that</p> <p>3 I did is the maximum hypothetical range</p> <p>4 based on FDA testing under even unrealistic,</p> <p>5 quote/unquote, worst case assumptions.</p> <p>6 BY MS. BOGDAN:</p> <p>7 Q. And you're referring to your reliance on the</p> <p>8 FDA laboratory analysis of valsartan products,</p> <p>9 correct?</p> <p>10 A. When I refer to "FDA testing," yes, that's</p> <p>11 what I'm referring to.</p> <p>12 Q. And the, quote, worst case scenario, to use</p> <p>13 your language, that you mentioned, was the highest</p> <p>14 value found by the FDA in the testing data it</p> <p>15 published with regard to contaminated valsartan</p> <p>16 products, correct?</p> <p>17 MR. INSOGNA: Objection, asked and</p> <p>18 answered. This was all covered in the prior</p> <p>19 deposition.</p> <p>20 THE WITNESS: So, yes, as I have</p> <p>21 testified to previously.</p> <p>22 BY MS. BOGDAN:</p> <p>23 Q. Which finished dose manufacturers use ZHP</p> <p>24 API for their valsartan finished pills?</p> <p>25 A. You cut out at the beginning. Could you</p>
<p style="text-align: right;">Page 59</p> <p>1 Q. I'm asking if you actually researched the</p> <p>2 average levels of NDMA or NDEA contamination</p> <p>3 associated with NDC codes?</p> <p>4 MR. INSOGNA: Objection, asked and</p> <p>5 answered.</p> <p>6 MS. BOGDAN: I don't believe he</p> <p>7 answered the question with regard to whether</p> <p>8 he attempted to ascertain the average or the</p> <p>9 range of NDMA or NDEA exposures associated</p> <p>10 with particular NDC codes.</p> <p>11 MR. INSOGNA: I believe that was --</p> <p>12 MS. BOGDAN: That's my question.</p> <p>13 MR. INSOGNA: I think that was the</p> <p>14 subject of the calculations we discussed in</p> <p>15 the last deposition.</p> <p>16 You can answer the question.</p> <p>17 THE WITNESS: So as we talked about</p> <p>18 in my last deposition, I calculated the</p> <p>19 maximum possible hypothetical range. We've</p> <p>20 talked about what the minimum was, less than</p> <p>21 96 nanograms per dose, and my understanding</p> <p>22 of NDC codes is that while it indicates an</p> <p>23 API manufacturer, that it does not indicate</p> <p>24 a specific lot and, therefore, you could</p> <p>25 not, from an NDC code, to my understanding,</p>	<p style="text-align: right;">Page 61</p> <p>1 repeat that?</p> <p>2 Q. Which finished dose manufacturers used ZHP</p> <p>3 API for valsartan finished pills?</p> <p>4 A. Sitting here now, I don't memorize that. I</p> <p>5 could go back through materials if you would like me</p> <p>6 to do that.</p> <p>7 Q. You don't know the answer, though, to that</p> <p>8 question, sitting here today?</p> <p>9 MR. INSOGNA: Objection to form.</p> <p>10 Asked and answered.</p> <p>11 THE WITNESS: I do not memorize that</p> <p>12 information, no.</p> <p>13 BY MS. BOGDAN:</p> <p>14 Q. Which finished dose manufacturers use Myland</p> <p>15 API for valsartan finished pills?</p> <p>16 MR. INSOGNA: Same objection.</p> <p>17 THE WITNESS: My calculations were</p> <p>18 based on -- these were where the -- yeah, I</p> <p>19 mean, this was Exhibit 7 from the past</p> <p>20 deposition.</p> <p>21 So those were the FDA numbers and</p> <p>22 that was as FDA referred to them and that</p> <p>23 was how I referred to them.</p> <p>24 BY MS. BOGDAN:</p> <p>25 Q. I'm asking, Doctor, if you know which</p>

<p style="text-align: right;">Page 62</p> <p>1 finished dose manufacturers used Myland API for 2 their valsartan finished pills? 3 MR. INSOGNA: Same objection. 4 THE WITNESS: Yeah, as I've said, I 5 have not memorized the correspondence 6 between the finished dose manufacturers and 7 the lots of drug that the FDA tested. 8 BY MS. BOGDAN: 9 Q. Which finished dose manufacturers used 10 Hetero API for valsartan finished dose? 11 MR. INSOGNA: Same objection. Also 12 beyond the scope of his report. 13 You can answer the question. 14 THE WITNESS: My calculations were 15 based on the FDA testing, Hetero Labs, as 16 well as the algorithm that was presented by 17 plaintiffs that also refers to Hetero Labs. 18 BY MS. BOGDAN: 19 Q. Do you know which finished dose 20 manufacturers used Hetero API in their 21 valsartan-containing drugs? 22 MR. INSOGNA: Same objection. 23 THE WITNESS: Again, I do not 24 memorize what that correspondence is. I am 25 referring to data that the FDA published,</p>	<p style="text-align: right;">Page 64</p> <p>1 Q. A Princeton Pharmaceutical product, correct? 2 A. That's correct. 3 Q. And that would be 20,190 nanograms found in 4 that 320-milligram Princeton tablet, correct? 5 A. That's correct. 6 Q. My question that I asked is, have you seen 7 any testing demonstrating that tablets made with ZHP 8 API have no NDMA in them? 9 MS. LOTMAN: Objection to form. 10 THE WITNESS: I don't recall, sitting 11 here today. 12 BY MS. BOGDAN: 13 Q. Have you seen any testing demonstrating that 14 any pills made with ZHP API had less than 15 96 nanograms of NDMA in them? 16 MR. INSOGNA: Same objection. 17 Rosemarie, you spent hours in the 18 last deposition discussing the levels of 19 specific lots. I'll give you a little bit 20 of leeway here, but we're not going to redo 21 that whole set of questioning. 22 MS. BOGDAN: Well, with regard to the 23 supplemental report there is a -- you know, 24 a majority and a big part of the report is, 25 again, discussing levels as it pertains to</p>
<p style="text-align: right;">Page 63</p> <p>1 which are -- is the same nomenclature that 2 is used in the plaintiffs' materials 3 proposing an algorithm by which to derive a 4 lifetime cumulative threshold. 5 BY MS. BOGDAN: 6 Q. For valsartan pills made with ZHP API, have 7 you seen any testing demonstrating that no NDMA was 8 found in those pills? 9 MR. INSOGNA: Objection to form. 10 This was also covered in the prior 11 deposition. 12 THE WITNESS: So in part in answering 13 your question, so as in my report, paragraph 14 21, I refer to Princeton Pharmaceutical 15 corresponding to the ZHP API from the 16 manufactured lot containing the highest 17 level of NDMA measured by the FDA in the 18 320-milligram valsartan product. 19 BY MS. BOGDAN: 20 Q. And what was that level? 21 A. The maximum level measured by the FDA in any 22 valsartan product, 320 milligrams was 23 20.19 micrograms per tablet. 24 Q. And that -- 25 A. And that was the maximum in a specific lot.</p>	<p style="text-align: right;">Page 65</p> <p>1 the plaintiffs' medical monitoring, so I 2 believe I have every right to ask these 3 questions. They are completely cured off 4 the supplemental report and they go towards 5 the medical monitoring class and -- 6 MR. INSOGNA: All of the -- all of 7 the discussion of levels refers back to the 8 prior report, which you deposed him on for 9 ten hours. I think we've more than covered 10 this. 11 I will give you a little bit of 12 leeway, but if it continues to be questions 13 about levels observed and internal testing 14 versus FDA reporting, we're not going to 15 redo those questions. 16 Dr. Chodosh, you can answer this 17 question if you remember it. 18 THE WITNESS: So let me clarify, as 19 it says in my report, "As detailed in this 20 supplemental report, my opinions regarding 21 plaintiffs' request for medical monitoring 22 for cancer follow any straightforward manner 23 from the opinions expressed in my report of 24 August 2nd, 2021, regarding the question of 25 whether ingestion of valsartan products</p>

<p style="text-align: right;">Page 66</p> <p>1 affects the risk of developing cancer, which 2 is attached as Exhibit C. Where applicable, 3 my response to each element of plaintiffs' 4 third amended medical monitoring class 5 action complaint refers to the relevant 6 sections of my report of August 2nd, 2021." 7 Which is to say, in each place in my 8 supplemental report where I am referring to, 9 you know, numbers, calculations, whatever it 10 may be, I cite that paragraph, the section 11 of my original expert report that that is -- 12 that serves as the foundation for that. 13 So the foundation of those things 14 hasn't changed since my original report that 15 we spent a great many hours talking about, 16 the FDA-measured doses and doses measured by 17 manufacturers. 18 BY MS. BOGDAN: 19 Q. For the purposes of the supplemental report 20 that you have now provided, did you review any of 21 the finished dose manufacturers internal documents, 22 which indicate levels of NDMA or NDEA that they 23 found in their products? 24 MR. INSOGNA: Are you asking about 25 subsequent to the prior deposition where he</p>	<p style="text-align: right;">Page 68</p> <p>1 "Other sources show levels as high as 2 60.2 micrograms of NDMA," with footnote 3 number 6, which lists a ZHP number. 4 So that's an internal number and the 5 rest of Dr. Madigan's statement is "and 6 5.4 micrograms of NDEA," with the footnote 7 7 that refers to a "Torrent-related" document. 8 So, again, internal documents and 9 those numbers, those additional numbers that 10 Dr. Madigan is citing in addition to the FDA 11 numbers that he cites, same numbers that I 12 cite, those are -- those are numbers that, 13 as I recall, I've seen before in the 14 original reports from Dr. Panigraphy and 15 others. 16 And those were the things that we 17 discussed back in September at great length. 18 BY MS. BOGDAN: 19 Q. In reviewing Dr. Madigan's report in 20 preparation for your supplemental report that you 21 have now served in this litigation, did you review 22 those underlying documents that Dr. Madigan is 23 citing to in those footnotes 6 and 7 in his report? 24 A. In this case I did not, because I believe I 25 have seen those values referenced by some</p>
<p style="text-align: right;">Page 67</p> <p>1 testified to what he had reviewed? 2 MS. BOGDAN: I'm asking for the 3 purposes of the supplemental medical 4 monitoring report that Dr. Chodosh has 5 issued, if he is relying on and/or reviewed 6 any manufacturers' internal testing data 7 with regard to the levels of contamination 8 that they found in their drugs, product or 9 substance? 10 MR. INSOGNA: Objection, compound and 11 partially asked and answered at the prior 12 deposition. 13 THE WITNESS: So as we spoke about 14 for several hours back in September about my 15 original report, we talked at length about 16 internal testing documents that I had looked 17 at and my choice of FDA evaluations of NDMA 18 and NDEA levels in my calculations. And the 19 only thing subsequent to that deposition 20 would be, for instance, as noted in 21 Dr. Madigan's report, on page 2 of 22 Dr. Madigan's report, where as a footnote he 23 refers to sentences -- well, Dr. Madigan 24 cites the FDA levels, same levels that I 25 have cited, and then he appends to that</p>	<p style="text-align: right;">Page 69</p> <p>1 plaintiffs' experts before, that's number one. So I 2 will take at his word that Dr. Madigan was -- was 3 citing those accurately, especially since those 4 numbers are generally familiar to me. 5 And I also would not have done that because 6 the difference of threefold for NDMA or roughly 7 fourfold for NDEA would not make a difference for my 8 opinions that those levels of exposure are far below 9 what would be associated with an increased risk of 10 cancer. 11 Q. Since your last deposition, have you made 12 inquiries as to how many lots of the finished dose 13 medications were tested for NDMA or NDEA by each of 14 the defendant manufacturers? 15 A. I'm not sure what you're asking me. Are you 16 asking me testing subsequent to some date or 17 products manufactured subsequent? I -- I'm not sure 18 what you're asking me. 19 Q. Since I last deposed you, which was, I 20 believe, in October of 2021 -- 21 A. No, September 29th and September 30th. 22 Q. September. Okay. Right. It was right at 23 the end, okay, so in September of 2021. 24 Have you made any inquiry to ascertain how 25 many lots of the finished dose medications were</p>

<p>Page 70</p> <p>1 tested by the defendant manufacturers for NDMA or 2 NDEA? 3 A. How many lots from when? 4 Q. At any point in time. I'm asking if after 5 the depositions that we had in September, if you 6 made any inquiry as to the number of lots of 7 finished dose medications that were tested by the 8 defendants in this case for NDMA or NDEA? 9 A. If you're referring to the period of time 10 that preceded the final recall, I did not, since 11 that deposition, ask for additional information and 12 nor would it have changed my opinion. 13 Q. Since your last deposition, have you made 14 any inquiry as to how many lots of the API were 15 tested by each of the defendant manufacturers for 16 levels of NDMA or NDEA? 17 A. Since the last deposition, I have not 18 inquired about that type of testing and, again, nor 19 would it have changed my opinion in this matter. 20 MS. BOGDAN: Please pull up 21 exhibit -- I believe, it might be entitled 22 FDA control -- no, it's "Laboratory Analysis 23 of Valsartan Products." 24 TRIAL TECHNICIAN: Counsel, would it 25 be under any other name?</p> <p>Page 71</p> <p>1 MS. BOGDAN: I don't think so. Let's 2 just go off the record so I can just check 3 on this exhibit. 4 THE VIDEOGRAPHER: Off the record at 5 11:11. 6 (Brief recess.) 7 THE VIDEOGRAPHER: We are back on the 8 record at 11:13 a.m. 9 MS. BOGDAN: What exhibit are we up 10 to now? 11 TRIAL TECHNICIAN: This is Exhibit 6. 12 (Document marked for identification 13 as Chodosh Deposition Exhibit No. 6.) 14 BY MS. BOGDAN: 15 Q. Okay, Doctor, let me know once you can see 16 this exhibit. 17 A. Yes, I can see it. 18 Q. Are you familiar with this document? 19 A. Yes, I am. 20 Q. And directing your attention to the second 21 page of the document? 22 A. Yes. 23 Q. And then the third page of the document? 24 A. Yes. 25 Q. Are these the FDA testing levels that you've</p>	<p>Page 72</p> <p>1 been referring to? 2 A. Yes. 3 Q. If we could go back to the second page of 4 the document. 5 With regard to the manufacturer Aurobindo, 6 do you see that on the second page of the document? 7 A. Yes, I do. 8 Q. And there are three rows for Aurobindo right 9 at the top, correct? 10 A. Yes, I see that, yes. 11 Q. FDA is indicating that it tested nine total 12 lots for Aurobindo in those three rows? 13 MR. INSOGNA: Yeah, you asked these 14 exact questions at the last deposition. You 15 went through this document and asked how 16 many lots by each manufacturer were tested. 17 It's page 96 of the September 29th 18 deposition. 19 BY MS. BOGDAN: 20 Q. In lots they're tested? 21 A. You're asking me again? 22 Q. Asking you again because I need it as a lead 23 in, in to my next question. 24 A. For those three rows listed as "Aurobindo 25 Pharma," there are nine lots listed by the FDA as</p> <p>Page 73</p> <p>1 having been tested. 2 Q. Other than those nine test results that are 3 on this FDA document for purposes of your 4 supplemental report, did you rely on any other 5 testing results for Aurobindo product? 6 A. I relied on no other testing results beyond 7 those of the FDA, beyond the fact of my expectation 8 that Dr. Madigan, and both referring to the FDA 9 numbers himself for his report, as well as the ZHP 10 and the Torrent values that he listed that I 11 factored in, that if there had been other levels, 12 I'm confident that plaintiffs' experts would have 13 told me what they were if they were higher. 14 But as I -- we discussed for seemingly hours 15 at my last deposition, the FDA measurements of the 16 lots listed from the companies listed in this 17 document is what I relied upon for the calculations 18 that I presented. Whether those numbers are twofold 19 or threefold or fourfold different, if plaintiffs 20 wanted to propose that that would not change my 21 opinion in this matter that plaintiffs, who had 22 taken such products, would not be at an increased 23 risk of cancer. 24 Q. Okay. 25 MS. BOGDAN: Move to strike the</p>
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1 latter part of that.
2 BY MS. BOGDAN:
3 Q. My question was simply, for your
4 supplemental report did you rely on any testing
5 levels for Aurobindo product, other than what are
6 shown in this FDA laboratory analysis of valsartan
7 products that's been marked Exhibit 6?
8 MR. INSOGNA: Objection, asked and
9 answered.
10 THE WITNESS: I just answered you.
11 If you'd like, perhaps, it could be read
12 back.
13 BY MS. BOGDAN:
14 Q. It's a simple question, you know, with
15 regard to what testing levels you have relied on for
16 your supplemental report.
17 And I'm asking this line of questioning to
18 find out if you rely for your supplemental report,
19 on any testing levels other than the FDA levels that
20 are shown on this document for the lots that are
21 shown on this document?
22 MR. INSOGNA: Same objection.
23 You can answer again.
24 THE WITNESS: And as I answered you,
25 I used the FDA information in this document,

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1 as well as looking at the numbers that
2 Dr. Madigan cited and my expectation that if
3 there had been higher numbers, that your
4 experts felt were important to consider,
5 that I would have seen them, and that the
6 only two numbers that I saw, I factored that
7 into my consideration.
8 And those were from Dr. Madigan's
9 report, they were not in the FDA report.
10 And I factored them in, insofar as I could
11 see those levels compared to the FDA levels
12 and determined that those levels, even if I
13 were to accept those as listed in
14 Dr. Madigan's citations, would not have
15 changed my opinions in this case.
16 BY MS. BOGDAN:
17 Q. Okay. So since your deposition in September
18 that was over two days, you haven't taken into
19 consideration any other testing levels, other than
20 the ones that are shown on what's been marked as
21 Exhibit 6?
22 MR. INSOGNA: Objection, misstates
23 testimony.
24 THE WITNESS: I'm -- this is, I
25 think, the fourth time you've asked this

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1 exact question. I've given you an answer
2 each of the three previous times. I'm not
3 sure if the issue is you don't understand
4 what I've said, I don't know how to -- I
5 can't give you a different answer than what
6 I gave. I gave you the truthful answer to
7 your question three times.
8 BY MS. BOGDAN:
9 Q. Doctor, I'm not actually trying -- I'm
10 trying to sort of just be able to ask this and move
11 on.
12 We did discuss this at your last deposition
13 and I just want to make sure since your last
14 deposition you haven't taken into consideration any
15 other testing levels, other than what's shown on
16 this document that's been marked as Exhibit 6.
17 I'm asking about anything that you've done
18 since September up until now that would be
19 additional or different than what you did up to the
20 point of your last deposition.
21 MR. INSOGNA: Objection, misstates
22 testimony.
23 THE WITNESS: That is not -- that is
24 not what I -- that was not in the first
25 three answers to my question to you, put the

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1 way that you summarized it.
2 I was very clear, and I was very
3 clear that what's additional is looking at
4 your expert's reports, and particularly
5 Dr. Madigan, and the numbers that he cited
6 that are not FDA numbers so I could factor
7 that into my overall opinion.
8 And I've given you this answer now
9 four times. There is no other answer to the
10 question.
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
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23 BY MS. BOGDAN:
24 Q. Now, you testified that you did not know
25 what assays that the defendant manufacturers used

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1 when testing for levels of NDMA and NDEA in their
2 drug substance and drug products, correct?
3 A. I'm sorry, the beginning of your question
4 cut out. Could you repeat your question, please?
5 Q. You have testified that a concern of yours
6 is that you did not know the assay method that was
7 used by the defendant manufacturers in testing their
8 drug substance and drug products, correct?
9 A. Based on my last deposition that was one of
10 the reasons that I brought up why I chose to use FDA
11 testing data of manufactured lots of finished
12 product on the United States market, as opposed to
13 testing data from individual companies where there
14 were many unknowns so that was one of the reasons.
15 Q. Do you have any information that leads you
16 to believe that the defendant manufacturers were not
17 competent at using the FDA prescribed methods to
18 test for NDMA and NDEA in their drug products and
19 drug substance?
20 MR. INSOGNA: Objection, asked and
21 answered at the last deposition. On page
22 110, you asked him if he found reliable the
23 testing the defendants did on their own
24 product. I think we've covered all of this
25 ground.

<p style="text-align: right;">Page 94</p> <p>1 MS. BOGDAN: I think the question is 2 actually different and it's a basis for his 3 medical monitoring opinion and the levels 4 he's relying on. I'm asking if he's learned 5 any information that would cause him to 6 believe that the defendant manufacturers 7 were not competent in using testing methods 8 to detect NDMA and NDEA in their drug 9 substance and product. 10 MR. INSOGNA: You can answer this 11 question. 12 I'm excited to get to his actual 13 opinions in this case, but that's fine. 14 THE WITNESS: So as we talked about 15 for what seemed like hours at my last 16 deposition, we articulated -- I articulated 17 for you the list of reasons why I chose to 18 use FDA data, as opposed to data from 19 manufacturing companies. 20 And parts of those -- some of those 21 reasons, not to be inclusive, were that the 22 testing procedures themselves recommended by 23 the FDA changed over those periods of time, 24 such that I wouldn't know which -- which 25 version or which assay was being used, how</p>	<p style="text-align: right;">Page 96</p> <p>1 that we're still talking about this. 2 BY MS. BOGDAN: 3 Q. I think there was a disconnect with the 4 question that I asked and the answer that I 5 received. 6 My question was: Is in your investigation 7 and research into this case, if you learned any 8 information that the testing results that the 9 manufacturers came to using their testing methods 10 were unreliable or faulty? 11 MR. INSOGNA: Same objection. 12 BY MS. BOGDAN 13 Q. Not why -- not why you chose to use the FDA 14 test results, we have been over that. 15 What I'm asking is, in all of the documents 16 you reviewed in your list of materials considered, 17 et cetera, did you learn any information during your 18 investigation of this case that led you to believe 19 that the manufacturer's testing results were not 20 reliable or accurate? 21 MR. INSOGNA: Same objection. 22 THE WITNESS: And as I have testified 23 to, since I don't know the assay that was 24 used, the calibration methods, the equipment 25 that was used, the time in which the assays</p>
<p style="text-align: right;">Page 95</p> <p>1 familiar the people performing the testing 2 were, how they were calibrating it, what the 3 instruments were that they were performing 4 these on, as well as my experience as a 5 laboratory scientist, that even given 6 exactly the same written protocol when 7 performed by different scientists in 8 different laboratories that more often than 9 not a different answer will be gained. 10 And, therefore, you cannot compare 11 those numbers between manufacturers tested 12 at different sites using I don't know what 13 assays. And as I testified at length in my 14 last deposition, that the fact that the 15 people who developed the protocol, the FDA, 16 had measured many lots of manufactured drugs 17 that were available on the US market and 18 that could be linked up to times when they 19 were on the US market, such that I could 20 calculate highest hypothetical worst case 21 scenarios, those data are far superior, in 22 my opinion, to make a determination of 23 exposures. 24 We went through all of this ad 25 nauseam and I have to say it's disappointing</p>	<p style="text-align: right;">Page 97</p> <p>1 were performed or any standard sets of NDMA 2 or NDEA reference samples that were shared, 3 I have every expectation, based on all of my 4 scientific experience for the past 45 years, 5 that those numbers would not be comparable 6 to other manufacturers and I have no way to 7 assess whether they were done in a reliable 8 fashion using a reliable assay. 9 BY MS. BOGDAN: 10 Q. And that's true even if they were using a 11 validated method, is that your opinion? 12 MR. INSOGNA: Same objection. That 13 exact question was answered. 14 THE WITNESS: I don't know what you 15 mean by "a validated method." 16 BY MS. BOGDAN: 17 Q. A method that has been scientifically tested 18 and determined to be accurate through validation 19 procedures that are done at the laboratory? 20 A. I'm sorry, that -- the way that you've asked 21 that question is too vague for me to give you an 22 answer. 23 Q. Let's go to your report, which is Exhibit 4, 24 to paragraph 26. 25 A. Yes.</p>

<p style="text-align: right;">Page 98</p> <p>1 Q. In that paragraph you are providing the 2 maximum periods of time that valsartan products 3 potentially containing NDMA and NDEA were available 4 on the US market, correct? 5 A. That's correct. 6 Q. Okay. And so you are stating there were 51 7 months for potentially containing NDMA product on 8 the market, correct? 9 A. That's correct. 10 Q. Seventy-five months for valsartan products 11 potentially containing NDEA on the market? 12 A. Yes, that's correct, as I wrote in my 13 original report and as I testified to during our 14 prior deposition on this. 15 Q. So if we take the highest level of 16 contamination that was found by the FDA in its 17 laboratory analysis for NDMA, that would be 18 20.19 micrograms, correct? 19 MR. INSOGNA: Objection. 20 THE WITNESS: 20.19 micrograms was 21 the highest level measured by the FDA. The 22 highest level of NDMA measured in an FDA -- 23 in a manufactured product, in a 24 320-milligram valsartan product. 25 BY MS. BOGDAN:</p>	<p style="text-align: right;">Page 100</p> <p>1 about medical -- 2 THE WITNESS: Do you have Exhibit 8? 3 Do you have Exhibit 8 from the prior 4 deposition? 5 MR. INSOGNA: The document Bates 6 labeled Chodosh 008, I forget what number it 7 was marked as. I can tell you what number. 8 It was Exhibit 18 of the September 29th 9 deposition, I believe. 10 MS. BOGDAN: I'm sorry, what? 11 MR. INSOGNA: Exhibit 18 of the 12 September 29 deposition, which are 13 Dr. Chodosh's calculations. 14 MS. BOGDAN: Nick? 15 MR. INSOGNA: It was Exhibit Number 16 18. 17 MS. BOGDAN: Exhibit 18? 18 MR. INSOGNA: Eighteen, 1-8, yes, 19 Bates labeled Chodosh 008. 20 BY MS. BOGDAN: 21 Q. Yes I -- I pulled that exhibit back up and 22 my question is, which I do not believe is answered 23 on this exhibit, is if a patient took a valsartan 24 320-milligram tablet with approximately 25 20 micrograms of NDMA for 51 months, that would</p>
<p style="text-align: right;">Page 99</p> <p>1 Q. So, hypothetically, if a plaintiff took a 2 20.19-microgram contaminated 320-milligram valsartan 3 tablet for the 51 month time period that you 4 indicated the valsartan products potentially 5 containing NDMA were on the market, what would be 6 the total cumulative exposure to NDMA? 7 MR. INSOGNA: Objection, 8 mischaracterizes the document. 9 THE WITNESS: So the -- so these 10 calculations were calculations that we 11 discussed at my last deposition and that are 12 described in detail in my original report in 13 this matter. 14 So are we going back to that now? 15 BY MS. BOGDAN: 16 Q. Well, let me just -- so, you know, if a 17 patient took a 300-milligram valsartan tablet with 18 approximately 20 micrograms of NDMA in it for 51 19 months, that would equal 30,600 micrograms of total 20 NDMA, correct? 21 MR. INSOGNA: Object to form. 22 Mischaracterizes the document and asked and 23 answered at the prior deposition. 24 MS. BOGDAN: I do not believe that 25 this was. And since we're talking</p>	<p style="text-align: right;">Page 101</p> <p>1 equal over 30,000 micrograms of NDMA, correct? 2 Now, I don't see that calculation on this 3 exhibit and I'm using the FDA number, which is what 4 the doctor has said he's relied on and the number of 5 months that the doctor has represented in paragraph 6 26 of his supplemental report that the valsartan 7 products potentially containing NDMA were available 8 on the US market. 9 MR. INSOGNA: Objection, that 10 mischaracterizes his calculation. 11 But you can answer that question, 12 Dr. Chodosh. 13 THE WITNESS: So if you want to 14 understand the calculation, let's go to my 15 original report -- 16 BY MS. BOGDAN: 17 Q. I don't understand the calculation, no. 18 A. That's what the calculation is. 19 Q. I'm sorry? 20 A. I calculated the maximum theoretical amount 21 of -- that a person taking the highest available 22 dose of a valsartan product for the 1611 days, I 23 believe it was, what that amount would be. And then 24 on my original report, paragraphs 136 and following, 25 I did a calculation based on -- let me find it.</p>

<p style="text-align: right;">Page 102</p> <p>1 Q. And what was that total exposure of --</p> <p>2 A. Sorry, I wasn't finished my answer. I</p> <p>3 apologize for the pause.</p> <p>4 Did a calculation based on the albeit</p> <p>5 unrealistic assumption of what the theoretical</p> <p>6 maximum total amount of NDMA to which plaintiffs</p> <p>7 could conceivably have been exposed from any</p> <p>8 valsartan product produced by any combination of</p> <p>9 manufacturers where I assume that on any given day a</p> <p>10 theoretical plaintiff took the valsartan product</p> <p>11 available on the market.</p> <p>12 MR. INSOGNA: Rosemarie, can you --</p> <p>13 MS. BOGDAN: That's not me.</p> <p>14 MR. INSOGNA: Sorry. For the</p> <p>15 feedback. Our room just lost power.</p> <p>16 THE VIDEOGRAPHER: Off the record --</p> <p>17 off the record at 12:15.</p> <p>18 (Luncheon recess.)</p> <p>19 THE VIDEOGRAPHER: We are back on the</p> <p>20 record at 1:06 p.m.</p> <p>21 BY MS. BOGDAN:</p> <p>22 Q. Good afternoon, Doctor.</p> <p>23 A. Good afternoon.</p> <p>24 Q. Can you hear my audio okay? I'm just</p> <p>25 checking that you can hear me --</p>	<p style="text-align: right;">Page 104</p> <p>1 I think before we took the break because the</p> <p>2 power went out, we were -- you were looking back on</p> <p>3 your previous report and one thing that I just want</p> <p>4 to make clear, a lot of the questions I'm asking are</p> <p>5 attempting to find out if you have done anything</p> <p>6 different or looked at more documents or changed</p> <p>7 what you're basing your opinion on since I last</p> <p>8 deposed you, all right?</p> <p>9 So when I'm asking you these questions,</p> <p>10 that's what I'm trying to get to, if there's</p> <p>11 something additional you did after the last time I</p> <p>12 deposed you on these issues. I can read the report,</p> <p>13 but if there was some other activity or data you</p> <p>14 looked at or something you considered, then that's</p> <p>15 what I'm trying to glean by my questions, okay?</p> <p>16 So while we had this break, I went and</p> <p>17 pulled up your first report and in that report in</p> <p>18 paragraphs 137, you do a calculation for NDMA, a</p> <p>19 hypothetical scenario that corresponds to the</p> <p>20 theoretical maximum total NDMA exposure.</p> <p>21 Do you see that in your first report?</p> <p>22 A. Yes, I do.</p> <p>23 Q. Is that the calculation that you were</p> <p>24 referring to before the power went out as far as --</p> <p>25 A. That is the section of the report where I</p>
<p style="text-align: right;">Page 103</p> <p>1 A. It's very --</p> <p>2 Q. -- and I can hear you.</p> <p>3 A. It's a very loud and it's a bit choppy. Are</p> <p>4 we able to just -- how about now?</p> <p>5 MR. INSOGNA: Rosemarie, do you want</p> <p>6 to try to just say something for us and test</p> <p>7 the volume?</p> <p>8 MS. BOGDAN: Yeah, I'm just lowering</p> <p>9 my volume a little bit because it is a</p> <p>10 different dynamic.</p> <p>11 Does that help at all?</p> <p>12 MR. INSOGNA: It sounds a little bit</p> <p>13 garbled.</p> <p>14 THE WITNESS: Yeah, it's a little</p> <p>15 garbled and like metallic, like tinny.</p> <p>16 THE VIDEOGRAPHER: Would you like to</p> <p>17 go off the record?</p> <p>18 MS. BOGDAN: Sure.</p> <p>19 THE VIDEOGRAPHER: Off the record at</p> <p>20 1:07.</p> <p>21 (Pause.)</p> <p>22 THE VIDEOGRAPHER: We are back on the</p> <p>23 record at 1:09 p.m.</p> <p>24 BY MS. BOGDAN:</p> <p>25 Q. Dr. Chodosh -- okay.</p>	<p style="text-align: right;">Page 105</p> <p>1 walk through for NDMA and for NDEA separately, I</p> <p>2 walked through two scenarios for each, one related</p> <p>3 to Teva products and the maximum -- yeah, for</p> <p>4 products available during that period potentially</p> <p>5 contaminated with NDMA and then I walked through it</p> <p>6 with any valsartan product so that's, as I recall,</p> <p>7 what I was referring to.</p> <p>8 Q. Okay. And so -- I'm sorry, were you</p> <p>9 speaking? There was feedback going on.</p> <p>10 A. I started to speak, but I'll just wait for</p> <p>11 your next question.</p> <p>12 Q. Okay. I didn't mean -- the audio is a</p> <p>13 little delayed and funky so, hopefully, we can get</p> <p>14 through this and...</p> <p>15 So in paragraph 137 of your previous report,</p> <p>16 is -- does that paragraph have the maximum</p> <p>17 hypothetical scenario that corresponds to the</p> <p>18 theoretical maximum of total NDMA exposure?</p> <p>19 A. Yes, it does and I'm -- I am -- ah, okay.</p> <p>20 So, first, in answer to your question, yes,</p> <p>21 it is; and, second, and this is maybe why I'm so</p> <p>22 puzzled is that my supplemental report very</p> <p>23 specifically refers to these paragraphs and the</p> <p>24 calculation.</p> <p>25 So I wasn't -- my supplemental report, I</p>

<p style="text-align: right;">Page 106</p> <p>1 think, is pretty clear, and, again, in my paragraph 2 36, "As discussed in detail in my report of August 3 2nd, 2021," and then at the end of that I reference 4 paragraphs 132 to 137, 142, 148 to 153. 5 Similarly, with the next paragraph that I 6 felt that I was very clear in my supplemental report 7 that there was nothing new about those calculations, 8 those were presented in my original report, you 9 deposed me on those and I was simply referring to 10 them. And in that same way, that was the intention 11 of my statement when I said that my opinions follow 12 in a straightforward manner from the opinions 13 expressed in my report of August 2nd. 14 So there are no -- there aren't -- I didn't 15 redo calculations. This is predicated on the 16 original report and those calculations. 17 Q. So for the purpose of the medical monitoring 18 claim, the theoretical maximum total exposure to 19 NDMA which a plaintiff could conceivably have been 20 exposed to is 26,635 micrograms? 21 MR. INSOGNA: Object to form. 22 THE WITNESS: 26,635 micrograms 23 refers to the hypothetical, if the 24 completely unrealistic set of assumptions 25 that somehow a theoretical plaintiff managed</p>	<p style="text-align: right;">Page 108</p> <p>1 it does not change my opinion that it's 2 still not capable of increasing cancer risk. 3 BY MS. BOGDAN: 4 Q. In your opinion what cumulative exposure to 5 NDMA would increase a person's cancer risk? 6 A. So we talked about this as well at length in 7 my original deposition for a period of time and so 8 I'm -- if you want to revisit that, I'm happy to 9 revisit that. 10 Q. Let me ask the question another way. 11 What cumulative exposure to NDMA with regard 12 to the medical monitoring claim is it your opinion 13 would increase the risk to warrant medical 14 monitoring? 15 MR. INSOGNA: Objection to form. 16 THE WITNESS: So I've answered before 17 that what I was asked to evaluate was 18 whether the doses of NDMA or NDEA to which 19 plaintiffs could conceivably have been 20 exposed as a consequence of ingesting 21 valsartan products is not within orders of 22 magnitude, not within orders of magnitude of 23 what might be associated with an increased 24 risk. 25 So as I testified in my original</p>
<p style="text-align: right;">Page 107</p> <p>1 to take the valsartan product on the market 2 on that day that had the highest amount of 3 NDMA, which I layout, I think, very clearly 4 in my report. 5 I do not consider those to be 6 realistic assumptions. It is presented 7 merely as an example that even if that takes 8 the unrealistic scenario that I've just laid 9 out, that that would be the amount. And I 10 believe as I have also said both in my 11 report and in my testimony at my last 12 deposition and, I believe, in the 13 supplemental report that whether one changes 14 it -- well, I've already said it today. 15 If one changes that number to twofold 16 or threefold or fourfold, it does not make a 17 difference in terms of risk and, therefore, 18 does not change my opinion that those values 19 are so far below any doses of NDMA ever 20 shown to cause cancer in any system, no 21 matter how sensitive. They're so far below 22 it that whether you're, you know, that 23 level, the 26635, which I already believe is 24 a gross overestimate, even if one were 25 looking at twofold or threefold or fourfold,</p>	<p style="text-align: right;">Page 109</p> <p>1 deposition, I was not asked nor did I opine 2 on what is -- what is the dose of NDMA that 3 might theoretically increase risk, that is 4 not the question that I opined on. I opined 5 on the question of the amounts that people 6 conceivably could have been exposed to. 7 And even erring with extremely 8 conservative estimates that the conclusion 9 that that is not within orders of magnitude 10 of what could be associated with an 11 increased risk. 12 BY MS. BOGDAN: 13 Q. With regard to providing your opinions 14 regarding the scientific and medical basis for 15 requests for medical monitoring for cancer, have you 16 formed an opinion as to what the cumulative exposure 17 to NDMA or NDEA would need to be in order to justify 18 medical monitoring? 19 MR. INSOGNA: Objection, asked and 20 answered. 21 THE WITNESS: So the answer I just 22 gave you would be the exact same answer. 23 BY MS. BOGDAN: 24 Q. And the reason I asked the question again is 25 I asked you with regard to NDEA as well.</p>

<p style="text-align: right;">Page 110</p> <p>1 A. Oh, I apologize then. Can you restate the 2 question? I did not pick that up. 3 Q. With regard to being asked to provide your 4 opinions regarding the scientific and medical basis 5 for the requests for medical monitoring, did you 6 determine a cumulative dose of NDEA that would 7 warrant medical monitoring? 8 A. For NDEA my answer is precisely analogous to 9 my opinion regarding NDMA, which was I was asked to 10 opine on whether the maximum hypothetical doses of 11 NDEA that plaintiffs could have been exposed to, 12 even using unrealistic, overly conservative 13 assumptions, are not within orders of magnitude of 14 doses that would be capable of causing cancer. 15 I was not opining on trying to determine a 16 specific level of NDEA at which even hypothetically 17 there might have been an increased risk. 18 Q. So for the medical monitoring opinion that 19 you're offering, you have not determined any 20 particular exposure that results in increased risk 21 of cancer? 22 MR. INSOGNA: Objection, asked and 23 answered. 24 THE WITNESS: What I determined was 25 that the maximum theoretical cumulative</p>	<p style="text-align: right;">Page 112</p> <p>1 that these things are capable of causing cancer in 2 human beings. But to the extent that there were 3 estimates, I have presented the maximum hypothetical 4 amounts both in relation to normal dietary intake, 5 exposures from food, air and water relative to 6 potential endogenous exposures and then relative to 7 the lowest dose of NDMA or NDEA that could cause 8 cancer in the most sensitive animal species in the 9 most sensitive tissue within that species. 10 And so recognizing that the cumulative 11 amounts in this litigation that have been alleged if 12 they are not within a hundredfold, a thousandfold, 13 10,000-fold of that level, that's what I mean by 14 "nowhere in the vicinity." 15 Q. And when you're speaking to that are you 16 referring to your medical monitoring report, 17 paragraph 41, where you're talking about the dosage 18 in rats that would correspond to an exposure of 19 60,850,650 micrograms over a 70-year lifetime for a 20 70-kilogram person? 21 A. So it is paragraph 41 of my supplemental 22 report, which references my original report from 23 August 2nd, 2021, for paragraphs 132 to 137, 142, 24 and 154 to 156. So there's, of course, a forward 25 explication of where those numbers come from in my</p>
<p style="text-align: right;">Page 111</p> <p>1 exposures using worst case assumptions and 2 overly conservative assumptions, were that 3 those values, those cumulative amounts of 4 NDMA or NDEA are nowhere vaguely in the 5 vicinity of a dose that could cause cancer 6 in a human being or a mammal for that 7 matter. 8 BY MS. BOGDAN: 9 Q. When you say they're not the doses in -- in 10 the vicinity of the doses that would increase risk 11 to warrant medical monitoring, can you provide a 12 range or any type of quantitative analysis as to how 13 much NDMA or NDEA that would be? 14 A. So with the proviso, I believe, that the 15 answers I have given you are my best and most 16 truthful answers. The values derived that -- that 17 the -- if you will, that the FDA uses for linear 18 low-dose extrapolation that I included in my 19 calculations. 20 And they're in both my original report, 21 they're in my supplemental report, that effectively 22 says that given a dose -- well, let me start -- let 23 me take one step back. 24 Neither NDMA nor NDEA is a known human 25 carcinogen, so there's no -- there's no evidence</p>	<p style="text-align: right;">Page 113</p> <p>1 original report that we spent quite a bit of time 2 talking about back in September. 3 Q. With regard to the medical monitoring claim, 4 do you -- and I recognize that you're citing to your 5 previous report -- you are using the same analysis 6 to the dosage in rats and converting that to a human 7 dose in order to come up with the orders of 8 magnitude that you're speaking of? 9 MR. INSOGNA: Object to form. 10 THE WITNESS: My sense is your 11 description of paragraph 41 is largely 12 correct. I would only say that, yes, I have 13 done that in the same way that the FDA and 14 EMA and Health Canada has done that, that 15 is, converting the dose in milligrams per 16 kilogram from the Peto 1991 study or studies 17 to what a human dose -- a human equivalent 18 to that would be. 19 MS. BOGDAN: Have we marked 20 Dr. Madigan's report as an exhibit yet? I 21 don't believe we have. 22 TRIAL TECHNICIAN: Just the 23 supplemental report. 24 MS. BOGDAN: All right. Could you 25 please mark Dr. Madigan's report as an</p>

<p style="text-align: right;">Page 114</p> <p>1 exhibit. And if you could, remind me what 2 number we're on. I believe it's number 34 3 in order in the repository. 4 TRIAL TECHNICIAN: That's Exhibit 10. 5 MS. BOGDAN: If we could go to the 6 first page of the actual report. I don't 7 know, Doctor, if this is available for you 8 to see it yet, but... 9 THE WITNESS: Yes, it is. I can see 10 it. 11 (Document marked for identification 12 as Chodosh Deposition Exhibit No. 10.) 13 BY MS. BOGDAN: 14 Q. Is this the report of Dr. Madigan that you 15 reviewed and comment on in your medical monitoring 16 report? 17 A. I believe it is. The only reason that I'm 18 pausing is that the hard copy that I have has a date 19 under the signature and so -- but other than that, 20 let me just make sure that this is -- 21 Q. That looks like it's really faint on there. 22 Looks like it might be July 7th, 2021? 23 A. Yes. Oh, okay. Yeah, I can't see that. 24 Yes, I believe it is the same report. 25 Q. And did you thoroughly review this report as</p>	<p style="text-align: right;">Page 116</p> <p>1 Q. Based on your review of the studies and the 2 table, you didn't find any inaccuracies to your 3 knowledge, correct? 4 A. If by "inaccuracies" you mean do I believe 5 he misrepresented one of the numbers? No, but, 6 again, with the proviso that I couldn't always find 7 what the particular number was that he found. And 8 I'll also say that there were, you know, instances 9 in which while the number that he selected from the 10 paper versus the number that I saw, you know, I did 11 not -- in those instances, I was largely writing my 12 opinions to say if -- if he has represented this 13 correctly, what would it actually say about risk, 14 because he notes in his report that there were 15 instances in which he's done his own calculations. 16 And so, therefore, not everything -- it's 17 not simply that he identified a number in a report, 18 that there were instances in which he was indicating 19 that he was doing his own calculations. 20 (Zoom interruption.) 21 MS. BOGDAN: Are we still on the 22 record and everybody can hear? 23 THE VIDEOGRAPHER: We are still on 24 the record. Please continue. 25 BY MS. BOGDAN:</p>
<p style="text-align: right;">Page 115</p> <p>1 part of your preparation for your medical monitoring 2 supplemental report? 3 A. Yes, I did. And I think as is evident in my 4 supplemental report, I reference Dr. Madigan's 5 wording throughout. 6 Q. Now, turning your attention to Table 1, 7 which is on page 7 of the report. 8 A. Yes. 9 Q. And did you review this table? 10 A. Yes, I did. And as I've said, I think 11 there's a discussion of data from this table in my 12 supplemental report. 13 Q. And did you review the underlying studies to 14 see where Dr. Madigan was getting the values that 15 are in Table 1 on page 7 of his report? 16 A. So for the great majority of these, yes 17 there were, I believe, instances in which I had a 18 bit more of a challenge in figuring out exactly 19 which number from the paper that he had taken and 20 for those I made the assumption that he is 21 accurately representing data. 22 Q. And upon your review you didn't find any 23 misrepresentations of the data based on your review 24 of the studies and review of the table, correct? 25 A. Could you say that again, please?</p>	<p style="text-align: right;">Page 117</p> <p>1 Q. Now, do you see the column in Table 1 of 2 LCE? 3 A. Yes, I do. 4 Q. What do you understand that to represent? 5 A. That stands for "Lifetime Cumulative 6 Exposure." 7 Q. And the lifetime cumulative exposures in 8 that column are associated with particular studies, 9 correct? 10 A. Yes. "Associated with," meaning they were 11 derived in some way from the study on the same row 12 of that table; is that what you mean? 13 Q. Yes. 14 A. Yes. 15 Q. And those values range from a low of 3,343 16 on the table, you see that or actually there's -- 17 strike that. Let me ask this another way. 18 In the plaintiffs' medical monitoring plan 19 it lists a level of exposure of cumulative NDMA of 20 1,962 micrograms; is that your understanding? 21 A. I'm sorry, can you say that again? 22 Q. In the plaintiffs' proposed medical 23 monitoring plan it lists a cumulative exposure of 24 1,962 micrograms of NDMA as the value that 25 significantly raises the risk of cancer and warrants</p>

<p>Page 118</p> <p>1 lifetime medical monitoring. 2 Are you aware of that? 3 A. Could you point me to that? Could you point 4 me to that, please, what you are referring to? 5 Q. I'm referring to paragraph 28. 6 A. So I'm looking at paragraph 28 and I believe 7 the sentence that you're referring to, please 8 correct me if I'm wrong, "Consequently, it is 9 difficult to reconcile the FDA's assessment that 10 lifetime cumulative exposure to 2,454 micrograms of 11 NDMA is safe (an assessment with which Plaintiffs' 12 expert Dr. Madigan agrees) with Plaintiffs' claim 13 that lifetime cumulative exposure to 14 1,962 micrograms of NDMA significantly raises the 15 risk of cancer and warrants lifetime medical 16 monitoring for cancer." 17 So is that what you're referring to? 18 Q. What I'm referring to is the value of 19 Dr. Madigan's of 1,962 and your understanding of 20 what study that comes from? 21 A. I understand what study that number came 22 from, which -- hold on one second -- is Larsson but, 23 of course, it only appears as a footnote to his 24 table. He did not include it in the table proper. 25 Q. Okay. And in the footnote to the table it</p>	<p>Page 120</p> <p>1 cumulative figures that are listed by Dr. Madigan in 2 Table 1, correct? 3 A. If you are asking me is the total cumulative 4 hypothetical maximum exposure that I calculated 5 under all of the various overly conservative and 6 unrealistic assumptions, if you're asking me is that 7 number greater than some of the numbers in this 8 table, yes, that is correct. 9 However, given that Dr. Madigan's opinion is 10 internally contradictory, I have a very hard time 11 assigning a great deal of meaning to that. But if 12 what you are asking about is one number larger than 13 another number, yes, one number is larger than 14 several of the other numbers. I don't think it has 15 biological significance and apparently neither does 16 Dr. Madigan. 17 Q. Well, you can't testify to Dr. Madigan's 18 opinion. 19 But my question is, you calculated that to 20 be 26,640 micrograms, correct? 21 A. I'm sorry, I disagree with the premise. I 22 can testify to what is in Dr. Madigan's report. And 23 he says very clearly that the FDA ADI, he agrees, is 24 a safe level. And yet, the figure of 25 1,962 micrograms, is lower than what Dr. Madigan</p>
<p>Page 119</p> <p>1 notes that the "Larsson study is also significant 2 for the third quintile to first quintile contrast"? 3 A. You've read that correctly, yes. 4 Q. And LCE of 1,962 micrograms, correct? 5 A. Yes. 6 Q. Now, given your calculations of the 7 potential exposure that patients taking contaminated 8 valsartan with NDMA, isn't it possible that 9 plaintiffs can reach the LCEs that are shown in 10 Table 1, associated with the studies that have a 11 statistically significant increased risk? 12 MR. INSOGNA: Objection to form. 13 THE WITNESS: I guess I'm not 14 understanding your question. 15 BY MS. BOGDAN: 16 Q. Well, part of your analysis with regard to 17 the medical monitoring claim was to calculate what 18 plaintiffs' potential exposure could be to NDMA from 19 their valsartan-containing drugs, correct? 20 A. Yes, that's correct. 21 Q. And part of that analysis would be 22 determining the potential levels of exposure. 23 And so my question is, the potential levels 24 of exposure that you have calculated for plaintiffs 25 taking valsartan to NDMA exceed the lifetime</p>	<p>Page 121</p> <p>1 says is a safe level. 2 So I can testify to the internal 3 contradiction in Dr. Madigan's own report. 4 Q. Back to the question I was asking and then 5 we will get to that, but the potential worst case 6 scenario exposure to NDMA you calculated was 7 26,640 micrograms, correct? 8 A. That is -- excuse me -- that is what I 9 calculated labeled, quote/unquote, worst case 10 scenario, which was a -- very explicitly a 11 hypothetical based on a series of assumptions that 12 would have to be met. 13 And as I stated in my report and in my 14 supplemental report, it's very unlikely that anyone 15 actually ever reached that level. 16 Q. That number of 26,640 micrograms is 17 significantly higher than the LCE listed for the 18 Palli study, which is with the first study in the 19 chart, correct? 20 A. Yes. 21 Q. And it's significantly higher than the 22 DeStefani study, which is the second study in the 23 chart, correct? 24 A. Yes, as I've already answered in response to 25 your questions, that number 26,000 -- 26,635 is</p>

<p style="text-align: right;">Page 122</p> <p>1 higher than nearly all of the numbers in this 2 dietary epidemiology table. So as a matter of math, 3 is number A bigger than number B, yes, I agree with 4 that number is bigger. I do not believe it has 5 biological significance. 6 Q. And with regard to Dr. Madigan's notation of 7 "SS?"; do you see that as a column heading? 8 A. Yes, I see that column heading. 9 Q. Do you know what that stands for? 10 A. My recollection is that that stands for 11 "Statistically Significant," question mark, but I 12 would have to go back and look to be sure. 13 Q. I will represent to you it stands for -- you 14 are correct -- statistical significance. 15 And Dr. Madigan noted several of these 16 studies in Table 1 that have statistically 17 significant results; isn't that true? 18 A. One second. So of the -- by my count, at 19 least, of the 25 studies listed here half or list 20 than half are statistically significant. 21 So, yes, some of them are statistically 22 significant. 23 Q. You reviewed those statistically significant 24 studies as part of your investigation into this 25 matter for purposes of the medical monitoring,</p>	<p style="text-align: right;">Page 124</p> <p>1 Did I read that correctly? 2 A. Yes, you did. 3 Q. And is part of your opinion in that regard 4 for medical monitoring based on exogenous dietary 5 exposure to NDMA? 6 A. Yes, that is one of the types of exposures 7 that I discuss in this section. 8 Q. And in your medical monitoring report you 9 speak to that in paragraphs 30, 31 and 32? 10 A. Yes. 11 Q. You rely in footnote 10 and in the text of 12 your medical monitoring report itself on the Liteplo 13 WHO 2002 Nitrosodimethylamine "Concise International 14 Chemical Assessment Document," correct? 15 A. That is the reference in paragraph 32, which 16 also cites -- I'll take a look -- paragraph 91 of my 17 original report. 18 Q. And you specifically mentioned that study in 19 paragraph 32 of your medical monitoring report, 20 correct? 21 A. I do and there are other -- so, yes, I do, 22 there are other estimates of dietary exposures 23 beyond Liteplo that are cited in the supplementary 24 report and were cited in my original report. 25 Q. Footnote 4, which is Tricker; footnote 5,</p>
<p style="text-align: right;">Page 123</p> <p>1 correct? 2 MR. INSOGNA: Object to form. 3 THE WITNESS: As I have said -- 4 BY MS. BOGDAN: 5 Q. You are offering your medical monitoring 6 opinion, I'm sorry. 7 There's a -- 8 A. I'm sorry, we're cutting in and cutting out. 9 Could you just repeat your question one more 10 time? 11 Q. I'll rephrase it. I think the audio got 12 dropped a little bit. 13 For purposes of rendering your medical 14 monitoring opinion, you reviewed those studies as 15 noted in Dr. Madigan's Table 1 that had 16 statistically significant increased risk findings, 17 correct? 18 A. Yes, as I've said, I've looked at the vast 19 majority of these studies. 20 Q. According to your medical monitoring report 21 page 8, section titled "Plaintiffs' claimed 22 dose/duration/API thresholds for medical monitoring 23 for cancers are orders of magnitude lower than 24 levels of NDMA, NDEA and other nitrosamines to which 25 humans beings are routinely exposed."</p>	<p style="text-align: right;">Page 125</p> <p>1 Biaudet; footnote 6, Dich; footnote 7, Fristachi; 2 footnote 3, Hrudey or Hrudey, if that's how it's 3 pronounced, correct? 4 A. Yes, remind me which -- or could you tell me 5 which paragraph you are looking at? Is that the 6 supplemental report? 7 Q. Yes, it's all in your supplemental report 8 and I'm referring -- I was just referring to the 9 references that you have specifically listed on your 10 supplemental report and I believe they're references 11 3 through 9. 12 A. Okay, but I asked you -- I was asking you if 13 you could just point me to which paragraph of my 14 supplemental report. 15 Q. Oh, I was reading -- 16 A. Is it paragraph 30? 17 Q. -- from 30 is where it starts. 18 A. Yeah, okay. 19 Q. And then it goes through like 33 in my 20 estimation and in paragraph 30 of your supplemental 21 report, is where you have the majority of the 22 footnotes 3 through 9 in the first sentence of 23 paragraph 30 in your report. 24 A. Yes, thank you. 25 Q. So referring to the -- you pronounce it</p>

<p style="text-align: right;">Page 126</p> <p>1 Liteplo, Liteplo study?</p> <p>2 A. I pronounce it Liteplo, but I have no idea</p> <p>3 how it's actually pronounced.</p> <p>4 MS. BOGDAN: Okay. Liteplo study, if</p> <p>5 we could pull that up, please, number 18.</p> <p>6 Plaintiffs' number 18 in the document</p> <p>7 repository.</p> <p>8 TRIAL TECHNICIAN: Got it. Thank</p> <p>9 you.</p> <p>10 (Document marked for identification</p> <p>11 as Chodosh Deposition Exhibit No. 11.)</p> <p>12 BY MS. BOGDAN:</p> <p>13 Q. Doctor, just let me know when you have the</p> <p>14 document.</p> <p>15 A. Yes, I do.</p> <p>16 Q. So you cite to this document, actually, as a</p> <p>17 reference to your medical monitoring report. I'd</p> <p>18 like you to direct your attention to page 4 of the</p> <p>19 document. Actually number 4, not Roman numeral IV.</p> <p>20 Thank you. All right.</p> <p>21 And in the second column, third paragraph</p> <p>22 down it reads, "Based upon laboratory studies in</p> <p>23 which tumors have been induced in all species</p> <p>24 examined at relatively low doses, NDMA is clearly</p> <p>25 carcinogenic."</p>	<p style="text-align: right;">Page 128</p> <p>1 with the statement. I understand you are</p> <p>2 adding the qualifier about medical monitor</p> <p>3 and I'm not going to instruct him not to</p> <p>4 answer.</p> <p>5 MS. BOGDAN: Okay.</p> <p>6 THE WITNESS: My opinions remain the</p> <p>7 same. Again, the phrase "relatively low</p> <p>8 levels of exposure" has no meaning as</p> <p>9 written since we measure levels of exposure.</p> <p>10 And since the levels of exposure that are</p> <p>11 alleged in this litigation are so many</p> <p>12 orders of magnitude lower than the doses to</p> <p>13 which Liteplo is referring, I -- no, I do</p> <p>14 not agree with that, nor do I believe that</p> <p>15 the author would agree with that if you</p> <p>16 actually used the quantitative number.</p> <p>17 "Relatively low levels of exposure,"</p> <p>18 does not have meaning here.</p> <p>19 BY MS. BOGDAN:</p> <p>20 Q. All right. If we can move to page 12 of the</p> <p>21 document, please, and in your medical monitoring</p> <p>22 report at paragraph 32, you refer to this study for</p> <p>23 "reasonable worst-case estimates" for daily intake</p> <p>24 of NDMA from food, water and outdoor air?</p> <p>25 A. That's correct.</p>
<p style="text-align: right;">Page 127</p> <p>1 Dr. Chodosh, do you agree with that</p> <p>2 statement?</p> <p>3 MR. INSOGNA: Objection, Rosemarie,</p> <p>4 asked and answered at his September</p> <p>5 deposition, that exact question.</p> <p>6 THE WITNESS: So NDMA is clearly not</p> <p>7 carcinogenic in human beings and "relatively</p> <p>8 low dose" has no scientific meaning.</p> <p>9 So I can't agree or disagree with</p> <p>10 that statement as it is.</p> <p>11 BY MS. BOGDAN:</p> <p>12 Q. And is it your opinion for medical</p> <p>13 monitoring with regard to the last statement in that</p> <p>14 same paragraph, "Qualitatively, the mechanism of</p> <p>15 NDMA appears to be similar in humans and animals; as</p> <p>16 a result, it is considered highly likely that NDMA</p> <p>17 is carcinogenic to humans, potentially at relatively</p> <p>18 low levels of exposure."</p> <p>19 Is it still your opinion with regard to the</p> <p>20 medical monitoring cause of action that you disagree</p> <p>21 with that statement?</p> <p>22 MR. INSOGNA: Same objection. In the</p> <p>23 September deposition at pages 380 to 396, is</p> <p>24 where you read statements from Liteplo and</p> <p>25 asked him whether he agreed or disagreed</p>	<p style="text-align: right;">Page 129</p> <p>1 Q. And the -- that you have in your medical</p> <p>2 monitoring report is from Section 6.2 and Table 2 of</p> <p>3 the study, which is on page -- the next page, page</p> <p>4 13; is that correct?</p> <p>5 A. That would appear to be correct looking at</p> <p>6 the column labeled "20 to 59 years" and the row</p> <p>7 labeled "Subtotals," that that amount is .005 to</p> <p>8 .016 micrograms per kilogram body weight per day and</p> <p>9 that corresponds to the numbers in paragraph 32 that</p> <p>10 you are referring to.</p> <p>11 Q. Okay.</p> <p>12 MS. BOGDAN: If the tech could please</p> <p>13 just move the exhibit to page 13. Okay.</p> <p>14 BY MS. BOGDAN:</p> <p>15 Q. Okay. And now that we have the exhibit up</p> <p>16 on the screen, you're referring to the values that</p> <p>17 are under the "20 to 59 year" category?</p> <p>18 A. Yes, as I just stated.</p> <p>19 Q. Yeah, we just didn't -- the technology</p> <p>20 wasn't keeping up with you, Dr. Chodosh.</p> <p>21 So -- and you derived the value for your</p> <p>22 report from the subtotal category that's "0.005</p> <p>23 through 0.016," which is the fourth category down</p> <p>24 under "20 to 59 years"?</p> <p>25 A. That's correct.</p>

<p style="text-align: right;">Page 130</p> <p>1 Q. Now, a whole section of this study and this 2 table are "reasonable worst-case estimates," 3 correct? 4 A. That is how it is labeled, yes. 5 Q. Okay. And in the footnotes under the table, 6 the authors expand on the conditions and where 7 they're getting these estimates from, correct? 8 A. That appears to be correct. 9 Q. And in the section of the report that 10 precedes this table and the section that references 11 this table that it's included in, if we could just 12 go back to page 12, in the second paragraph on the 13 right-hand side of the page, about two-thirds of the 14 way down that paragraph, it reads -- 15 MS. BOGDAN: Got to go a little 16 further than that. All right. There we go. 17 All right. 18 BY MS. BOGDAN: 19 Q. "Based on the assumptions underlying the 20 reasonable worst-case estimates, most of the daily 21 intake could be attributed to consumption of food 22 contaminated with NDMA during processing, 23 preservation and/or preparation." 24 Did I read that correctly? 25 A. Yes, you read it correctly.</p>	<p style="text-align: right;">Page 132</p> <p>1 so that as far as I can tell, most of the dietary 2 studies use very similar and older databases of 3 food. 4 And I dealt with this at length in my 5 original report, as well as reference to it in my 6 supplemental report. 7 Q. Are you aware that the food industry, in 8 general, has tried to lower the amount of nitrites 9 in processed foods in the last 20 years? 10 MR. INSOGNA: Object to form. 11 THE WITNESS: What I am aware of are 12 discussions of efforts to reduce amounts in 13 some foods, but I have not seen any 14 substantial body of data indicating that 15 that has happened or that just other things 16 haven't been substituted. 17 So the -- my -- the issues -- the 18 shortcomings of dietary studies and what 19 Dr. Madigan relies upon for his LCE 20 estimates, I do not accept those dietary 21 studies as a reliable basis to demonstrate 22 or determine or guess at a threshold of NDMA 23 exposure that might be associated in a human 24 being with increased risk. 25 So they're all subject to the same</p>
<p style="text-align: right;">Page 131</p> <p>1 Q. And then the authors go on to say, "It 2 should be noted, though, that the data on which the 3 estimates in food are based may not be 4 representative of the situation today, due to the 5 impact of subsequent introduction of changes in food 6 processing and controls to limit formation in food." 7 Did I read that correctly? 8 A. You read that correctly. 9 Q. So the authors are acknowledging that these 10 reasonable worst case estimates may not be 11 applicable to the situation today and the 12 publication of this study that was in 2002, correct? 13 A. The publication of this study was in 2002 14 and I spent some amount of time in my original 15 report and, I believe, referenced to in my 16 supplemental report, dealing with precisely this 17 issue of the uncertainty around dietary estimates of 18 NDMA content, how they are never a measurement in 19 any of the studies that Dr. Madigan refers to, they 20 are never a measurement of actual NDMA. 21 We've discussed that those are the best 22 estimates that are out there and while there is some 23 reason to believe that levels may have declined over 24 time in food stuffs, there are exceedingly few 25 measurements to actually demonstrate that, so much</p>	<p style="text-align: right;">Page 133</p> <p>1 uncertainties and the same lack of 2 measurement. 3 BY MS. BOGDAN: 4 Q. But you're relying on dietary studies to 5 support your opinion with regard to the amount of 6 exogenous exposure to NDMA through a person's diet, 7 correct? 8 MR. INSOGNA: Objection to form. 9 THE WITNESS: So I dealt with this 10 very specifically in my original report, 11 paragraph 86, "Precise quantification of 12 dietary exposures to pre-formed NDMA and 13 other nitrosamines in food is extremely 14 difficult, in part, because concentrations 15 of NDMA and other nitrosamines in different 16 foods change over time, can differ by 17 geographic region and are affected by 18 numerous variables, including the method of 19 preparation or preservation. In addition, 20 the types of foods consumed, as well as 21 serving sizes, vary widely between 22 individuals and data derived from 23 self-reporting and dietary questionnaires 24 are notoriously inaccurate. It is also 25 reasonable to note, that dietary exposures</p>

<p>Page 134</p> <p>1 relative to cancer development likely 2 occurred decades prior to cancer diagnosis." 3 And then here's the key that 4 references your question, paragraph 87, 5 "With these caveats in mind, reasonable 6 estimates of daily dietary intake of NDMA 7 can be made." 8 And then I go on to cite the numbers 9 that we are now talking about. 10 So I think I was exceedingly clear in 11 my report and as referenced from my 12 supplementary report of what the uncertainty 13 is around these numbers. And as an example, 14 I have used these numbers to point out how 15 extraordinarily low these exposures to NDMA 16 are in relationship to doses of NDMA that 17 are capable of causing cancer in a mammal, 18 in even the most sensitive mammal and the 19 most sensitive tissue. 20 BY MS. BOGDAN: 21 Q. Doctor, with all due respect, my question 22 was, will you rely on dietary studies to support 23 your opinion with regard to the amount of exogenous 24 NDMA people are exposed to through their diet? That 25 was the question, do you cite those reports as</p> <p>Page 135</p> <p>1 references for your section on endogenous formation 2 of -- excuse me -- exogenous exposure to NDMA? 3 MR. INSOGNA: Objection. 4 THE WITNESS: I apologize, but I did 5 not follow the question. 6 BY MS. BOGDAN: 7 Q. Okay. My -- and I'll reask it. 8 So my question was simply, in your medical 9 monitoring report with regard to your section that 10 addresses peoples' exposure to NDMA through their 11 diet, you reference in that section dietary studies 12 to support your opinion as to the levels of exposure 13 through the diet, correct? 14 A. I have cited to the studies that we've been 15 discussing and Liteplo, or as summarized in Liteplo, 16 to provide a rough estimate of what likely exposures 17 are from food, air and water and while detailing the 18 caveats surrounding how imprecise those estimates 19 are. 20 Q. So going back to the Liteplo study and the 21 incorporation in your report in paragraph 32 of the 22 "Reasonable worst-case estimates" that you derive 23 from Table 2, which is on page 13. 24 Would you agree that worst case estimates of 25 daily intake of NDMA are not indicative of average?</p>	<p>Page 136</p> <p>1 A. Yeah, I don't have enough information to 2 answer your question. The range given there is 3 8,950 to 28,600 micrograms of exposure to NDMA over 4 a 70-year lifetime for 70-kilogram person based on 5 food, air and water, which is roughly in the 6 ballpark of the numbers given in the previous 7 paragraph of dietary intake ranging from 4,190 to 8 19,700-microgram. 9 Q. In paragraph 33 of your report, if we could 10 now, I guess, pull your report back up, which is 11 Exhibit 4. I would like to take paragraph 32 and 33 12 if we could. 13 So in paragraph 32 you are citing to the 14 Liteplo study and the table that we've already 15 discussed to get the values ranging from .005 to 16 .016 micrograms per kilogram per day, correct? 17 A. Yes, you've read those numbers correctly. 18 Q. And that's from the table that's entitled 19 "Reasonable worst-case estimates," correct? 20 A. I don't remember the title of the table. 21 Yes, that is in -- that is in the name of that 22 title. 23 Q. And then in paragraph 32 you go on to say 24 that "This would correspond to an 8,950 to 25 28,600 micrograms of exposure to NDMA over a 70-year</p> <p>Page 137</p> <p>1 lifetime for a 70-kilogram person," correct? 2 A. Yes, you've read that correctly. 3 Q. Okay. Then if we go to paragraph 33, right, 4 As above, in light of the estimates of lifetime 5 cumulative exposure to NDMA attributable to food, 6 air, water ranging from again 8,950 to 7 28,600 micrograms, correct? 8 A. Yes, you've read that correctly. 9 Q. But those lifetime cumulative exposures as 10 referenced in the Liteplo study are "reasonable 11 worst-case estimates," correct? 12 A. That is the label that Liteplo, et al., 13 gave. But, of course, if you look at Dr. Madigan's 14 table, Table 1, you can see we're on the same order 15 of magnitude of what the levels are where his are 16 just dealing with food. And if you look in the 17 previous paragraph, paragraph 31, I give a dietary 18 range from 4,190 to 19,700. 19 And I'm looking at Dr. Madigan's Table 1, 20 and what I'm seeing are values that go up to 31,000 21 and go down into the 3,343. So the ranges that 22 Dr. Madigan is citing in Table 1, in those dietary 23 studies are the same ranges that I am citing in my 24 report. 25 Q. Yeah, Dr. Madigan -- Dr. Chodos, I wasn't</p>
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<p>Page 138</p> <p>1 asking you about what Dr. Madigan cited. If you 2 could just please answer the question that I asked. 3 What I asked was, that in 33 you're quoting 4 8,950 to 28,600 micrograms of -- as an estimate of 5 the lifetime cumulative exposure to NDMA and you're 6 getting those values from a study that has those 7 values, but they're stating they are "Reasonable 8 worst-case estimates" of the daily intake; isn't 9 that correct? 10 MR. INSOGNA: Objection to form. 11 THE WITNESS: I guess the -- the way 12 I'm trying to answer your question is that 13 what you keep referring to as "Reasonable 14 worst-case estimates," that's language that 15 those authors used. And since that's a 16 completely relative term, I'm pointing out 17 that what those authors called "Reasonable 18 worst-case estimates," are in the same 19 vicinity both in what is in my report and 20 what is in Dr. Madigan's table of study 21 after study after study. 22 So what Liteplo et al., may have 23 referred to as "Reasonable worst-case 24 estimates," what I'm saying is, are not 25 terribly different since we're talking about</p>	<p>Page 140</p> <p>1 increased risk of cancer and that would be the 2 DeStefani study, the Pobel study, the LaVecchia 3 study, the Larsson study, the Keszle study, the 4 Zheng study, the DeStefani study, the Goodman study, 5 the Knekt study, the Loh-Rectal study and the Zhu 6 study. 7 MR. INSOGNA: Objection to form. 8 THE WITNESS: I'm sorry, was there a 9 question? If there was a question, I 10 apologize, I missed the question. 11 BY MS. BOGDAN: 12 Q. Doctor, you keep referencing that the levels 13 that you put in paragraph 33 of your medical 14 monitoring report are in the ballpark or similar to 15 what Dr. Madigan has as his lifetime cumulative 16 exposure estimates in Table 1, correct? 17 A. No, no, incorrect. Dr. Madigan's tables are 18 dietary studies. My understanding is that that's 19 diet and not food, air and water, which is what you 20 are referring to in Liteplo. The data that I 21 included about diet or as I've been trying to point 22 out to you in paragraph 30, that would be the apples 23 to apples comparison, I believe. 24 Paragraph 30, "As detailed in my report, 25 estimates of dietary intake of NDMA (excluding beer</p>
<p>Page 139</p> <p>1 apples and oranges here, diet versus food, 2 air and water. You know, if you look right 3 at -- look right around -- we're talking 4 about maybe a factor of two. 5 BY MS. BOGDAN: 6 Q. But you're taking values that are in the 7 study that the authors are calling "Reasonable 8 worst-case estimates," and then you, in paragraph 9 33, are adopting those as estimates of lifetime 10 cumulative exposure to NDMA; am I correct? 11 A. No, I'm sorry. I don't -- I disagree with 12 your premise. I am not -- what is the word you 13 used, "adopting those"? I'm not adopting those. 14 This is but one piece of evidence that I provided in 15 this report of various estimates of dietary intake, 16 of intake from food, air and water and how they 17 compare to estimates that Dr. Madigan is listing as 18 an LCE. 19 So if you're asking me was this one piece of 20 evidence that I considered in arriving at my 21 opinions, yes, it was one piece of evidence. 22 Q. So -- but I would point out as you are 23 referencing the LCEs that are in Dr. Madigan's 24 report that many of those LCEs as referenced in his 25 report come with a statistically significant</p>	<p>Page 141</p> <p>1 and tobacco) from seven studies yield an average 2 cumulative exposure of 4,190 micrograms over a 3 70-year lifetime for a 70-kilogram person." 4 Q. Yes, I see that in your report and, 5 similarly, that 4,190-microgram over a 70-year 6 lifetime for a 70-kilogram person is in the range of 7 several of the studies that show statistically 8 significant increased risk of cancer that are 9 indicated on Madigan's chart? 10 A. If your question is, is the number 4,190 in 11 a similar range as a number of the numbers in 12 Dr. Madigan's Table 1, my answer to that is, yes, 13 that's correct, mathematically. It still has no 14 biological significance for determining a threshold 15 of risk. 16 Q. Did you do a risk assessment with regard to 17 the exposure of NDMA that would cause cancer? 18 MR. INSOGNA: Objection, that exact 19 question was asked and answered in the prior 20 deposition. 21 BY MS. BOGDAN: 22 Q. Did you do a risk assessment -- 23 MS. BOGDAN: Let me -- well, my 24 questions are going to what the doctor did 25 between his deposition at the end of</p>

<p style="text-align: right;">Page 142</p> <p>1 September and now as we're sitting here in 2 March. 3 BY MS. BOGDAN: 4 Q. So when I ask that question with regard to 5 the medical monitoring claim, did you perform a risk 6 assessment? 7 A. Between the last time that you and I met on 8 September 29th and September 30th, I have not done a 9 different analysis of really any of the numbers in 10 this and this is why this supplemental report states 11 on page 1, that my conclusions "follow in a 12 straightforward manner" from my original report. 13 MR. INSOGNA: Rosemarie, if you're 14 done with the Liteplo study, I'm sure Peg 15 would appreciate a quick break. 16 MS. BOGDAN: Or if you want to take 17 five minutes, that would be fine. 18 MR. INSOGNA: I think five minutes 19 would be fine. 20 THE VIDEOGRAPHER: Off the record at 21 2:24. 22 (Brief recess.) 23 THE VIDEOGRAPHER: We're back on the 24 record at 2:32. 25 BY MS. BOGDAN:</p>	<p style="text-align: right;">Page 144</p> <p>1 actually. Let's take this one down. 2 Let's go to the Biaudet study, number 3 21. 4 TRIAL TECHNICIAN: And do you want to 5 make this Exhibit 12 or just remove Exhibit 6 11 and make this 11? 7 MS. BOGDAN: Your choice. 8 TRIAL TECHNICIAN: This will be 9 Exhibit 12 then. 10 MS. BOGDAN: Okay. 11 THE WITNESS: I have the old one. 12 This is -- 13 TRIAL TECHNICIAN: Excuse me, this is 14 Exhibit 13, I misspoke. 15 MS. BOGDAN: Okay. 16 (Document marked for identification 17 as Chodosh Deposition Exhibit No. 13.) 18 BY MS. BOGDAN: 19 Q. Doctor, do you see the "Mean Daily Intake of 20 N-Nitrosodimethylamines From Foods and Beverages in 21 France" study? 22 A. Yes, I do. 23 Q. Okay. And that's one of the studies that 24 you actually put as a reference cited in your 25 medical monitoring report, correct?</p>
<p style="text-align: right;">Page 143</p> <p>1 Q. Okay. Doctor, let's look at a couple of the 2 dietary studies that you cite in your medical 3 monitoring report as references. 4 MS. BOGDAN: If we could pull up the 5 Tricker study, please? 6 TRIAL TECHNICIAN: Counselor, I have 7 two Tricker studies. Could you be a little 8 more descriptive? 9 MS. BOGDAN: Sure. The number 20, 10 "Mean Daily Intake Of Volatile 11 N-Nitrosamines From Foods And Beverages in 12 West Germany." 13 TRIAL TECHNICIAN: Okay. This will 14 be marked as Exhibit 12. 15 (Document marked for identification 16 as Chodosh Deposition Exhibit No. 12.) 17 BY MS. BOGDAN: 18 Q. Okay, Doctor, let me know when you can see 19 that exhibit, please. 20 A. Yes, I can see it. 21 Q. Is this one of the studies that you -- 22 THE COURT REPORTER: Lost that last 23 word there, Counsel. 24 MS. BOGDAN: Actually, I don't -- I 25 think we have the wrong Tricker study</p>	<p style="text-align: right;">Page 145</p> <p>1 A. Yes. And, I believe, it is cited in 2 Liteplo, as well, as many other papers on dietary 3 studies. 4 Q. Directing your attention to the second 5 paragraph under "Introduction," which reads, "To 6 date, the carcinogenic properties of the 7 nitrosamines have been tested in 39 different animal 8 species: These included rats, mice, guinea pigs, 9 hamsters, dogs, rabbits, pigs, birds, amphibians, 10 fish and also five species of primate. None of 11 these species showed resistance to the action of 12 these compounds, and there is no reason why humans 13 should be an exception." 14 Do you agree with that statement in the 15 study? 16 A. I disagree with that statement for the same 17 reason I believe your plaintiffs' experts would, 18 which is dose. It is all about dose. Human beings 19 are never exposed to the levels of NDMA that were 20 administered to these 39 different animal species. 21 Q. Now, this study was done in France, correct, 22 in the late '80s, early '90s? 23 A. That's correct, 1987 to 1992. 24 Q. Are there different diets that populations 25 have in different countries? Is there variability</p>

<p>Page 146</p> <p>1 in diets in countries?</p> <p>2 A. I -- yes, there is variability across</p> <p>3 countries. There is variability within countries;</p> <p>4 there's variability across time; there's variability</p> <p>5 from person-to-person. Those were the quotes that I</p> <p>6 read to you before from my report.</p> <p>7 Q. Do you agree with me on that?</p> <p>8 A. I agree with you that what?</p> <p>9 Q. Diets vary country-to-country?</p> <p>10 A. Yes, I think that's fair to say.</p> <p>11 Q. And this study is also dealing with diets</p> <p>12 that predated 1992, correct?</p> <p>13 A. That's correct.</p> <p>14 Q. And diets change over time as well, correct?</p> <p>15 A. Yes, they do.</p> <p>16 MS. BOGDAN: If we could pull up the</p> <p>17 Dich study, it's number 22. That's not it.</p> <p>18 Actually, it's Dich, et al., "Dietary</p> <p>19 Intakes of Nitrate, Nitrite and NDMA in the</p> <p>20 Finnish." The last name of the author is</p> <p>21 D-I-C-H. That's not the right study either.</p> <p>22 Yeah, let's try another one. Set</p> <p>23 that aside.</p> <p>24 How about Fristachi,</p> <p>25 F-R-I-S-T-A-C-H-I, "Estimation of the total</p>	<p>Page 148</p> <p>1 and not getting it.</p> <p>2 MR. INSOGNA: Yeah, he still has the</p> <p>3 M7.</p> <p>4 MS. BOGDAN: Okay.</p> <p>5 TRIAL TECHNICIAN: Okay. One moment.</p> <p>6 I'll diagnose it.</p> <p>7 Try Exhibit 14 and if that doesn't</p> <p>8 work I'll make it 14A.</p> <p>9 THE WITNESS: Yes, now that's worked.</p> <p>10 BY MS. BOGDAN:</p> <p>11 Q. Do you recognize that study, Doctor, as one</p> <p>12 of the studies that you referenced in your medical</p> <p>13 monitoring report?</p> <p>14 A. Yes.</p> <p>15 Q. And this is a study regarding the NDMA</p> <p>16 attributable to drinking water, correct?</p> <p>17 A. Correct.</p> <p>18 Q. And why did you cite this report?</p> <p>19 A. Because if you look at Table 1, for</p> <p>20 instance, "Ingestion rates for selected foods and</p> <p>21 drinking water," this is solely not about drinking</p> <p>22 water. So cereal, dairy, fish, meat, vegetables,</p> <p>23 beer, formula, water, this -- yeah, or page 347,</p> <p>24 "NDMA concentrations in foods," "NDMA concentrations</p> <p>25 in powdered infant formula."</p>
<p>Page 147</p> <p>1 oral intake of NDMA."</p> <p>2 Do you see that study yet, Doctor?</p> <p>3 THE WITNESS: No, I do not.</p> <p>4 TRIAL TECHNICIAN: If you click</p> <p>5 refresh this will Exhibit 14.</p> <p>6 (Document marked for identification</p> <p>7 as Chodosh Deposition Exhibit No. 14.)</p> <p>8 THE WITNESS: Yeah, what I have is</p> <p>9 "M7R1 assessment and control of DNA reactive</p> <p>10 mutagenic impurities in pharmaceuticals to</p> <p>11 limit potential carcinogenic risk, which is</p> <p>12 a guidance for industry." I don't think</p> <p>13 that's the one.</p> <p>14 MS. BOGDAN: That's not it. That's</p> <p>15 not it. This is a study that you cited in</p> <p>16 your medical monitoring report. That's</p> <p>17 supposed to be up on the screen.</p> <p>18 THE WITNESS: Well, I can see it on</p> <p>19 the screen. I don't have it on my -- and</p> <p>20 this folder has not shown up yet.</p> <p>21 TRIAL TECHNICIAN: Doctor, click</p> <p>22 refresh and there will be a new Exhibit 14</p> <p>23 and that should be the same exhibit as you</p> <p>24 see on the screen.</p> <p>25 THE WITNESS: No, I'm refreshing it</p>	<p>Page 149</p> <p>1 So there are data in this paper not solely</p> <p>2 due to drinking water. Although, of course,</p> <p>3 drinking water factors into total exposure and if</p> <p>4 one looks at -- here we go, Table 4, "Average daily</p> <p>5 dose micrograms per kilograms day and proportional</p> <p>6 oral intake estimates for NDMA in foods and drinking</p> <p>7 water calculated from a generated sample of 10,000."</p> <p>8 So the -- I cited this because it deals with</p> <p>9 concentrations -- estimated concentrations of NDMA</p> <p>10 in foods and it's frequently cited by many studies</p> <p>11 that look at dietary epidemiology of NDMA.</p> <p>12 And I'm fairly confident it's also cited by</p> <p>13 Liteplo in the WHO2002 paper that you were</p> <p>14 discussing earlier.</p> <p>15 Q. Directing your attention to the third page</p> <p>16 of the document, which I believe has page number</p> <p>17 3343 in the upper left-hand corner, but it's very</p> <p>18 difficult to read.</p> <p>19 A. Yes.</p> <p>20 Q. That's the right page.</p> <p>21 All right. So directing your attention to</p> <p>22 the right-hand column, second paragraph down from</p> <p>23 the top that begins, "Although the chemistry and</p> <p>24 kinetics of in vivo NDMA formation are understood."</p> <p>25 Do you see that?</p>

<p>Page 150</p> <p>1 A. Yes, I do.</p> <p>2 Q. Do you believe the chemistry and kinetics of</p> <p>3 in vivo NDMA formation are understood?</p> <p>4 A. I believe it's reasonably well understood.</p> <p>5 Q. And what do you understand the chemistry and</p> <p>6 kinetics of in vivo NDMA formation to be?</p> <p>7 MR. INSOGNA: Objection to form.</p> <p>8 THE WITNESS: I have no idea based on</p> <p>9 that question what you're asking me.</p> <p>10 BY MS. BOGDAN:</p> <p>11 Q. Would you describe the chemistry and</p> <p>12 kinetics of in vivo NDMA formation?</p> <p>13 A. NDMA is formed endogenously as a consequence</p> <p>14 of normal physiological metabolism in many cells at</p> <p>15 very high levels compared to anything that we are</p> <p>16 exposed to in the diet. It is metabolized by a</p> <p>17 cytochrome P450 enzymes CYP2E1, which is present in</p> <p>18 a variety of tissues, but with principal metabolism</p> <p>19 within the liver due to delivery through the portal</p> <p>20 circulation from the stomach, if it's something that</p> <p>21 was ingested, or created by metabolic processes</p> <p>22 within cells.</p> <p>23 When metabolized by CYP2E1 and other</p> <p>24 enzymes, eventually, from some NDMA molecules a</p> <p>25 methyldiazonium ion will be created and the</p> <p>Page 151</p> <p>1 half-life of that methyldiazonium ion is</p> <p>2 relatively -- well, it's actually quite short.</p> <p>3 There is a small fraction of the total pool</p> <p>4 of NDMA that people are exposed to due to endogenous</p> <p>5 processes that is excreted as NDMA in a detectable</p> <p>6 form in the urine. There are estimates that I have</p> <p>7 referenced in my report, in both of my reports, of</p> <p>8 endogenous production based on a variety of</p> <p>9 parameters considered in modeling given the fact</p> <p>10 that one can actually detect the DNA adducts that</p> <p>11 form as a consequence of endogenous NDMA production.</p> <p>12 I don't know what your -- is there more</p> <p>13 information you would like?</p> <p>14 Q. So the -- you mentioned that NDMA has a --</p> <p>15 not NDMA, the methyldiazonium ion has a short</p> <p>16 half-life?</p> <p>17 A. That's correct.</p> <p>18 Q. Okay. What -- when you say "short</p> <p>19 half-life," what is the half-life or range for the</p> <p>20 half-life?</p> <p>21 A. My understanding of the approximate</p> <p>22 half-life of a methyldiazonium ion is probably less</p> <p>23 than a second.</p> <p>24 Q. And how would you describe the rate at which</p> <p>25 NDMA is metabolized in the body?</p>	<p>Page 152</p> <p>1 A. I missed a word. You were a little bit</p> <p>2 garbled. Can you repeat the question, please?</p> <p>3 Q. How would you describe the rate in which</p> <p>4 NDMA is metabolized in the body?</p> <p>5 A. The way you've -- I can't answer that</p> <p>6 question the way you've asked it. If you could</p> <p>7 clarify what you're asking, that would -- that would</p> <p>8 be helpful and I would be glad to try to answer.</p> <p>9 Q. Is NDMA rapidly metabolized?</p> <p>10 A. I don't know what you mean by "metabolism."</p> <p>11 Q. When I say "metabolism," I mean conversion</p> <p>12 into its reactive form, which would be the</p> <p>13 methyldiazonium ion?</p> <p>14 A. The rates of -- I can't give you -- off the</p> <p>15 top of my head, I can't give you a rate constant or</p> <p>16 the rate at which NDMA is metabolized through its</p> <p>17 pathways to generate formaldehyde or</p> <p>18 methyldiazonium. I can't give you a precise</p> <p>19 half-life for that off the top of my head sitting</p> <p>20 here today.</p> <p>21 Q. Once NDMA is metabolized into its reactive</p> <p>22 form, then the NDMA itself ceases to exist, correct?</p> <p>23 MR. INSOGNA: Objection to form. The</p> <p>24 exact question was asked and answered in the</p> <p>25 prior deposition.</p> <p>Page 153</p> <p>1 THE WITNESS: Yes, once a molecule of</p> <p>2 NDMA is metabolized, that original molecule</p> <p>3 of NDMA is no longer there.</p> <p>4 BY MS. BOGDAN:</p> <p>5 Q. And where do CYP2E enzymes exist in the</p> <p>6 body?</p> <p>7 A. When looking at cytochrome P450 enzymes,</p> <p>8 which are, sort of, the body's way of dealing with</p> <p>9 most chemical compounds, whether from within the</p> <p>10 body or outside the body, the liver is the organ</p> <p>11 that is principally responsible for metabolism of</p> <p>12 most things, but the CYP2E1 enzyme itself is</p> <p>13 expressed in a variety of tissues.</p> <p>14 I can't speak to the precise levels in each</p> <p>15 tissue that it might be expressed in.</p> <p>16 Q. Going back to that second paragraph in the</p> <p>17 right-hand column, the next part of that sentence</p> <p>18 is, "Inadequate data exists to accurately estimate</p> <p>19 the quantities of NDMA formed endogenously in</p> <p>20 humans."</p> <p>21 Do you agree with that statement?</p> <p>22 A. I disagree with that statement.</p> <p>23 Q. What is the basis for you disagreeing with</p> <p>24 that statement?</p> <p>25 MR. INSOGNA: Objection, that</p>
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<p style="text-align: right;">Page 154</p> <p>1 question was asked and answered at page 375</p> <p>2 of the prior deposition.</p> <p>3 You can answer it again.</p> <p>4 THE WITNESS: So if you look at my</p> <p>5 original report, paragraph 95, paragraph 96,</p> <p>6 paragraph 97, paragraph 98. So I would be</p> <p>7 glad to read those into the record, but that</p> <p>8 would be my, I think, reasonably detailed</p> <p>9 explication of what the basis for my</p> <p>10 opinions are about endogenous NDMA and the</p> <p>11 ability to measure it, since it references</p> <p>12 publications that have done just that and</p> <p>13 we've talked about them at some length.</p> <p>14 BY MS. BOGDAN:</p> <p>15 Q. For purposes of the medical monitoring cause</p> <p>16 of action, have you discovered any additional basis</p> <p>17 for your opinion with regard to disagreeing with the</p> <p>18 statement, "Inadequate data exists to accurately</p> <p>19 estimate the quantities of NDMA formed endogenously</p> <p>20 in humans"?</p> <p>21 A. In any other thing -- I have to go back and</p> <p>22 look exactly what I referenced in these sections,</p> <p>23 which I would be glad to do now, if you'd like. But</p> <p>24 otherwise, the basis would be within the same set of</p> <p>25 materials considered that were provided with my</p>	<p style="text-align: right;">Page 156</p> <p>1 if my voice cut out. See if I can find that</p> <p>2 sheet here. Number 19 in the document</p> <p>3 repository. There you go.</p> <p>4 TRIAL TECHNICIAN: This will be</p> <p>5 available as Exhibit 15.</p> <p>6 MS. BOGDAN: Thank you.</p> <p>7 (Document marked for identification</p> <p>8 as Chodosh Deposition Exhibit No. 15.)</p> <p>9 THE WITNESS: Okay. I can see it.</p> <p>10 BY MS. BOGDAN:</p> <p>11 Q. Now, this is a study that you cite as one of</p> <p>12 your references in your medical monitoring report,</p> <p>13 correct?</p> <p>14 A. Yes, it is and was cited in my original</p> <p>15 report as well.</p> <p>16 Q. And it's one of the bases of your opinion</p> <p>17 with regard to medical monitoring?</p> <p>18 A. If that's a question, yes. Is this one</p> <p>19 paper part of my opinions on medical monitoring,</p> <p>20 yes, this paper is a part of my opinion.</p> <p>21 Q. Now, in the what I would call "Abstract,"</p> <p>22 which is the summary right on that first page, it</p> <p>23 mentions that the "Analysis of ingested NDMA from</p> <p>24 food and water based on Monte Carlo modeling."</p> <p>25 Do you see that?</p>
<p style="text-align: right;">Page 155</p> <p>1 original report.</p> <p>2 I just can't tell you sitting here right now</p> <p>3 without going back and cross-checking whether or not</p> <p>4 I've referenced every one of those in the paragraphs</p> <p>5 that I just referred you to regarding endogenous</p> <p>6 NDMA formation.</p> <p>7 Q. My question is with regard to your opinion</p> <p>8 that you're offering for medical monitoring, is</p> <p>9 there anything in addition that you now have to</p> <p>10 support your testimony that you disagree with that</p> <p>11 statement aside from what you have in your</p> <p>12 supplemental report, your -- or your original</p> <p>13 report.</p> <p>14 Is there something new?</p> <p>15 MR. INSOGNA: Object to form, asked</p> <p>16 and answered.</p> <p>17 You can answer.</p> <p>18 THE WITNESS: As I just said, all of</p> <p>19 the data are on my materials considered list</p> <p>20 or lists. There's no new data since you</p> <p>21 deposed me at the end of September that I</p> <p>22 have -- that I am relying upon for this</p> <p>23 opinion.</p> <p>24 MS. BOGDAN: If we could now pull up</p> <p>25 the Hruday study, H-R-U-D-E-Y. H-R-U-D-E-Y,</p>	<p style="text-align: right;">Page 157</p> <p>1 A. If you give me a moment, I would like just</p> <p>2 to reread the abstract for myself since you are</p> <p>3 starting in the middle.</p> <p>4 Okay.</p> <p>5 Q. Okay. Do you see where it references a</p> <p>6 "Monte Carlo modeling" analysis?</p> <p>7 A. Yes, I do.</p> <p>8 Q. My question is, what is a Monte Carlo</p> <p>9 modeling analysis?</p> <p>10 MR. INSOGNA: Objection, outside the</p> <p>11 scope of his opinion.</p> <p>12 THE WITNESS: Monte Carlo analysis,</p> <p>13 to my understanding, is essentially a</p> <p>14 statistical approach taken to modeling data,</p> <p>15 but I can't speak more specifically about</p> <p>16 it.</p> <p>17 BY MS. BOGDAN:</p> <p>18 Q. Do you know how it's actually performed?</p> <p>19 MR. INSOGNA: Same objection.</p> <p>20 Dr. Chodosh is not here offering statistics</p> <p>21 opinions.</p> <p>22 THE COURT REPORTER: I'm sorry, Nick.</p> <p>23 I could not hear that objection.</p> <p>24 MR. INSOGNA: Sorry. I said,</p> <p>25 Dr. Chodosh is not offering statistics</p>

<p>Page 158</p> <p>1 opinions. He is not a statistician.</p> <p>2 BY MS. BOGDAN:</p> <p>3 Q. Other than it being a statistical analysis</p> <p>4 that's done, do you have any further, more specific</p> <p>5 idea as to how such Monte Carlo analysis is</p> <p>6 performed?</p> <p>7 A. My recollection is if given a large set of</p> <p>8 data, items of data that a Monte Carlo analysis can</p> <p>9 run multiple permutations of those data, dividing</p> <p>10 them in -- sequentially in different ways to compare</p> <p>11 what the result is for each iteration of that, but</p> <p>12 that's as much as I can tell you sitting here today.</p> <p>13 Q. Do you know why the authors of this study</p> <p>14 employed a Monte Carlo analysis?</p> <p>15 MR. INSOGNA: Object to the form,</p> <p>16 calls for speculation.</p> <p>17 THE WITNESS: The authors use three</p> <p>18 different types of data to estimate</p> <p>19 endogenous NDMA formation in humans and they</p> <p>20 presented what those estimates are for each</p> <p>21 of those three different methods, each of</p> <p>22 which were based on measurements. One of</p> <p>23 them -- one of them is based on NDMA levels</p> <p>24 in blood samples, so that's just a chemical</p> <p>25 measurement taken in combination with blood</p> <p>Page 159</p> <p>1 clearance rates.</p> <p>2 And the other looks at</p> <p>3 06-methylguanine levels in DNA from human</p> <p>4 blood cells. And then the third is based on</p> <p>5 urinary excretion. So for each of those</p> <p>6 very different approaches to estimating</p> <p>7 endogenous NDMA levels, there are</p> <p>8 mathematical models that need to be employed</p> <p>9 in order to estimate the thing you're trying</p> <p>10 to estimate, which in this case is how many</p> <p>11 micrograms of NDMA are produced in a human</p> <p>12 being everyday.</p> <p>13 So in the same way that for a patient</p> <p>14 who has a PET scan looking at radioactive</p> <p>15 glucose uptake, that -- those results are</p> <p>16 all based on modeling, on compartmental</p> <p>17 modeling, which is in some ways similar to</p> <p>18 this. You have to measure the rate at which</p> <p>19 something is entering the system and the</p> <p>20 rate at which something is leaving the</p> <p>21 system in order to calculate production</p> <p>22 rates, if that makes sense.</p> <p>23 BY MS. BOGDAN:</p> <p>24 Q. And modeling was used in this study in order</p> <p>25 to attempt to predict endogenous formation in</p>	<p>Page 160</p> <p>1 humans, correct?</p> <p>2 A. No, I would not agree with that</p> <p>3 characterization.</p> <p>4 Q. Why wouldn't you agree with that</p> <p>5 characterization?</p> <p>6 A. They weren't predicting concentrations, they</p> <p>7 were estimating concentrations based on three</p> <p>8 different methods. Those methods involve modeling,</p> <p>9 as does the great majority of things that are</p> <p>10 measured in human beings or in clinical practice.</p> <p>11 So they weren't predicting it, they were</p> <p>12 measuring it.</p> <p>13 Q. And is that because you can't actually</p> <p>14 measure NDMA forming in a person, meaning able to</p> <p>15 actually catch it as it forms and quantify it?</p> <p>16 MR. INSOGNA: Objection to form.</p> <p>17 THE WITNESS: There are most</p> <p>18 certainly studies that measure levels of</p> <p>19 NDMA. It's absolutely possible to measure</p> <p>20 that. The issue is you're not talking about</p> <p>21 steady state levels as in how much NDMA is</p> <p>22 there per milliliter of blood. The measure</p> <p>23 that these authors are after is how much is</p> <p>24 generated in a person per day, that's a</p> <p>25 rate, not a level. And so to get you a rate</p> <p>Page 161</p> <p>1 from a level, that that requires some</p> <p>2 modeling.</p> <p>3 And, I believe, when we talked about</p> <p>4 this in my deposition in September, I may</p> <p>5 have given the example of a bucket. And you</p> <p>6 have a bucket that has some level of water</p> <p>7 in it and water leaves that bucket at some</p> <p>8 rate and water enters that bucket at some</p> <p>9 rate. And if the level of water in that</p> <p>10 bucket stays the same and you can measure</p> <p>11 the amount that's leaving then you know the</p> <p>12 amount that's being added to the bucket.</p> <p>13 So that's just an example of what</p> <p>14 would be referred to as "modeling," but</p> <p>15 which, in fact, is done routinely in</p> <p>16 clinical medicine and human physiology, as</p> <p>17 well as in animals.</p> <p>18 BY MS. BOGDAN:</p> <p>19 Q. And that's because NDMA is forming, NDMA can</p> <p>20 be metabolized and then cease to exist, more can</p> <p>21 form and it's a dynamic system, correct?</p> <p>22 A. Correct, in that all things in human beings</p> <p>23 are dynamic. So sodium level in your bloodstream is</p> <p>24 actually dynamic. You don't have the same number of</p> <p>25 sodium molecules of -- ping-pong around in your body.</p>
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<p>Page 162</p> <p>1 There's stuff getting added and there's stuff that's 2 leaving, so it's the same for most physiological 3 things in a human being. 4 Q. Directing you to page 2186, the first 5 sentence in the first full paragraph on the left 6 side of the page where it says "The clearance rate 7 of NDMA has not been study directly in humans." 8 Is that true to your knowledge? 9 MR. INSOGNA: Object to form. 10 THE WITNESS: Give me a moment to let 11 me read -- look at the context. 12 Number one, so this was in 2013, so 13 in -- I would need to go back and look at 14 some more recent studies. 15 BY MS. BOGDAN: 16 Q. Right. 17 A. Including those from -- there were certainly 18 more recent studies on NDMA, so I can't speak to 19 whether or not a clearance rate in human being has 20 been directly studied. 21 But what this paragraph describes is that 22 the clearance rate of systemically applied NDMA has 23 been studied across species and that NDMA clearance 24 scales across those species as a function of body 25 weight. And as it says "Given a blood concentration</p> <p>Page 163</p> <p>1 and evidence that the concentration represents a 2 steady state, this clearance rate is a basis for 3 estimating a rate of endogenous formation of NDMA 4 using conventional pharmacokinetic models," which 5 just emphasizes that these -- the models that you're 6 referring to, this is standard fare for looking at 7 the flux of things in a human being, looking at the 8 flux of chemical compounds in a human being. 9 Q. Are you familiar with those Gombar studies 10 that are in that paragraph you just read? 11 A. I believe I have -- let's see what their 12 paper referenced. 13 Yeah, so in my materials considered list in 14 my original report, I list five different studies 15 from Gombar. Two in 1990, one in 1988, one in 1987 16 and another in 1988. I would be happy to read you 17 the titles of those. 18 So I have looked at those and these are 19 studies that are -- have been referred to in a 20 number of places throughout the literature, I'm 21 looking at NDMA levels in human beings. 22 Q. So the answer is you are familiar with the 23 studies? 24 A. I -- they're on my materials considered. I 25 believe, I have looked at those studies. I am not</p>	<p>Page 164</p> <p>1 intimately familiar with those nor have I committed 2 them to memory. 3 Q. Same page but down a little further, please. 4 Section -- 5 A. Can you tell me which page? I was going to 6 the references to look at the Gombar, what the 7 reference was. 8 So can you tell me what page again? 9 Q. 2186. 10 A. Okay. 11 Q. And the section numbered 2.3.5? 12 A. Yes. 13 Q. Which reads "Estimating endogenous rates of 14 N-Nitrosamine formation from their daily excretion 15 in urine is less certain as the amount eliminated in 16 urine is a very small fraction of that which is 17 ingested or formed endogenously." 18 Do you agree with that statement? 19 MR. INSOGNA: Object to form. 20 THE WITNESS: I generally do agree 21 with that statement and as Hrudey, et al., 22 state that their estimates -- this was the 23 third approach that they took to estimating 24 endogenous production levels, that the range 25 for this estimate based on urine</p> <p>Page 165</p> <p>1 concentrations that range was quite a bit 2 broader and for the first two methods, which 3 agreed quite well with each other. 4 And so I think they're referring to 5 that back in 2013, however, that being said, 6 for instance, current studies even in the 7 past year from FDA scientists, it's possible 8 to very accurately measure amounts of NDMA 9 in urine and the approximate concentrations 10 or what -- if you will, what fractions of 11 endogenous NDMA is excreted in the urine. 12 There are reasonably consistent 13 estimates of that and the technology for 14 measuring NDMA is far beyond now what it was 15 and what Hrudey is referring to back in 16 2013. 17 BY MS. BOGDAN: 18 Q. So the Florian study of 2021? 19 A. That is one of the studies. 20 Q. Jumping to page 2187, second column on the 21 right, starts with "Five studies," but the sentence 22 that I'm interested in reads -- it's about a third 23 of the way down, "Therefore, it seems reasonable 24 that these data indicate significant variation among 25 populations in the nature of endogenous</p>
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<p style="text-align: right;">Page 166</p> <p>1 N-nitrosamine formation."</p> <p>2 And then the next sentence is, "These</p> <p>3 geographic differences may be explained by many</p> <p>4 factors; genetic differences in the processes</p> <p>5 involved in either nitrosamine formation or</p> <p>6 metabolism, pre-existing disease processes,</p> <p>7 differences in diet or lifestyle, even the presence</p> <p>8 of trihalomethanes in drinking water because they</p> <p>9 are inhibitors/inducers of CYP2E1."</p> <p>10 Do you agree with those two sentences?</p> <p>11 A. I do not agree that those conclusions can be</p> <p>12 reached by the data presented here and specifically</p> <p>13 because they're discussing urinary excretion of NDMA</p> <p>14 in humans, which the same authors had pointed out</p> <p>15 that of the three methods that they used, that of</p> <p>16 those three methods, urinary excretion using</p> <p>17 technology available at those points in time was the</p> <p>18 least precise.</p> <p>19 So to me, the first two methods that they</p> <p>20 use which are not based on urinary excretion are the</p> <p>21 ones that enable an assessment of this issue. And</p> <p>22 my reading of the literature, would be that much in</p> <p>23 the metabolism of NDMA, whether across species, the</p> <p>24 enzymes involved, the levels of O6-methylguanine</p> <p>25 adducts or N7-methyl adducts are quite similar, even</p>	<p style="text-align: right;">Page 168</p> <p>1 So I just don't think based on these</p> <p>2 data that that would be a conclusion that I</p> <p>3 would have reached or think you can reach</p> <p>4 based on the data.</p> <p>5 BY MS. BOGDAN:</p> <p>6 Q. Does a person's diet influence the amount of</p> <p>7 endogenous formation of NDMA?</p> <p>8 A. Yes, it is influenced by diet.</p> <p>9 Q. Okay. If we could go to page 2197, please,</p> <p>10 the section entitled "Dietary Intake." The study</p> <p>11 actually estimate the daily dietary intake of NDMA</p> <p>12 in the US population.</p> <p>13 Do you see that in Section 5.2?</p> <p>14 A. Yes, I do.</p> <p>15 Q. And what do they estimate the daily dietary</p> <p>16 intake of NDMA in the US population to be?</p> <p>17 A. Yeah. So I believe that what is referenced</p> <p>18 in this paragraph for -- so Hrudey, et al., are</p> <p>19 providing their estimate of dietary intake and then</p> <p>20 they are pointing out that the intake that others</p> <p>21 have reported.</p> <p>22 And I believe that several of those are</p> <p>23 actually the references that I alluded to before.</p> <p>24 Q. In this study the authors are saying that</p> <p>25 the estimate of daily dietary intake of NDMA in the</p>
<p style="text-align: right;">Page 167</p> <p>1 going across species.</p> <p>2 So estimates -- well, I'll just leave it at</p> <p>3 that. So I think -- you don't use -- from my -- in</p> <p>4 my opinion, you don't use the least accurate</p> <p>5 measurement approach to draw conclusion about</p> <p>6 variation across a population.</p> <p>7 So I disagree with that statement for those</p> <p>8 reasons, among others.</p> <p>9 Q. Significant variation among populations due</p> <p>10 to diet regarding the level of endogenous NDMA that</p> <p>11 forms?</p> <p>12 MR. INSOGNA: Object to form.</p> <p>13 THE WITNESS: My point is that -- the</p> <p>14 way I'm trying to address your question, my</p> <p>15 point is, is that if you take an assay and</p> <p>16 approach to measuring a level and that's</p> <p>17 your least precise way to measure it and it</p> <p>18 intrinsically, just based on the nature of</p> <p>19 the assay, gives you a very broad range.</p> <p>20 They're -- in my opinion, if you then</p> <p>21 ask -- in different samples when I see</p> <p>22 variation in the levels, I do not think it</p> <p>23 is easily discernible whether that is due to</p> <p>24 the assay itself or whether that is due to</p> <p>25 some intrinsic aspect of the population.</p>	<p style="text-align: right;">Page 169</p> <p>1 US population ranges from 0.03 to 0.06 micrograms</p> <p>2 per day, depending on age, with adults aged 20 to 49</p> <p>3 years experiencing an exposure of 0.06 micrograms</p> <p>4 per day or 0.08 micrograms per day, if beer is</p> <p>5 included.</p> <p>6 MR. INSOGNA: Is that a question?</p> <p>7 BY MS. BOGDAN:</p> <p>8 Q. There's estimate?</p> <p>9 A. Yes, I wasn't sure if that was -- are you</p> <p>10 saying did you read that correctly, those numbers?</p> <p>11 Q. I'm saying the authors estimate, that's what</p> <p>12 my question was, did the authors estimate that the</p> <p>13 daily dietary intake of NDMA in the US population</p> <p>14 ranges from 0.03 to 0.06 micrograms per day</p> <p>15 depending on age with adults aged 20 to 49 years</p> <p>16 experiencing exposure of 0.06 micrograms per day or</p> <p>17 0.08 micrograms per day when beer is included?</p> <p>18 A. So you read that correctly and my</p> <p>19 recollection is that their estimate of .03 to</p> <p>20 .06 micrograms per day was one of the -- I believe,</p> <p>21 the six or seven values that I included in the</p> <p>22 average dietary intake, also including several of</p> <p>23 the other studies that they listed in this same</p> <p>24 paragraph, in order to arrive at an average estimate</p> <p>25 across these different dietary studies in different</p>

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1 countries, including the United States, in part to
2 reflect the fact that the majority of dietary
3 epidemiology studies of NDMA in cancer are not
4 performed in the United States, they are by and
5 large in other countries as is evident by looking at
6 Table 1 of Dr. Madigan's report.
7 So I viewed that as a representative then --
8 a set of dietary studies from similar countries as
9 they're being represented by the dietary
10 epidemiology studies.
11 Q. But this study unlike the others where we
12 have estimates in the German population or the
13 Finnish population or the French population, they
14 date back into the '80s or the '90s.
15 This study which is a 2013 study actually
16 provides an estimate of the dietary intake of the US
17 population, correct?
18 MR. INSOGNA: Object to form.
19 THE WITNESS: I would have to spend
20 more time going back through this to be able
21 to answer your question accurately.
22 BY MS. BOGDAN:
23 Q. Well, using the 0.06 micrograms per day,
24 which is the estimate that they provide for adults
25 aged 20 to 49 years, 0.06 micrograms a day would be

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1 60 nanograms per day, correct?
2 A. I'm sorry, can you say that again?
3 Q. 0.06 micrograms per day is the same as
4 60 nanograms per day, correct?
5 A. That's correct. That's correct.
6 Q. So if we take that 60 nanograms and we want
7 to know the total dietary intake over a 70-year
8 lifetime, we would take that 60, we would multiply
9 it by 365 days and then by 70 years, correct?
10 A. Predicated on the assumption that those
11 estimates are reasonably accurate estimates.
12 Q. And when we do that, we get a total dietary
13 intake over a 70-year lifetime of 1,533 micrograms?
14 A. If what you're saying is that instead of
15 surveying an average of dietary levels that have
16 been cited in the literature representing the
17 dietary epidemiology study, that instead of doing
18 that you cherry-pick one number, do you get a
19 different number than you do from the average, yes,
20 you do.
21 Q. I'm asking if we -- if we calculate the
22 total dietary intake over a 70-year lifetime using
23 the values that are now highlighted on the screen in
24 Hruday, we end up with a total dietary intake over a
25 70-year lifetime of 1,533 micrograms?

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1 A. From this one figure in this one paper the
2 math sounds grossly correct. That is not a number
3 that I would rely on.
4 Q. And that 1,533 micrograms of total dietary
5 intake over a 70-year lifetime is lower than the
6 value that the FDA provides based on their
7 96 nanograms per day, which results in a lifetime
8 cumulative exposure of 2,454 micrograms, correct?
9 A. If you're --
10 MR. INSOGNA: Object to form.
11 THE WITNESS: If you're asking me
12 does the FDA acceptable daily intake due to
13 pharmaceutical products of 96 nanograms per
14 day, you're asking me is that 70-year
15 cumulative total -- I believe, it's
16 2454 micrograms -- if you're asking me is
17 that different than this one number that
18 you're pointing to in this paper if you
19 calculate it out, yes, that is larger than
20 this one number.
21 BY MS. BOGDAN:
22 Q. Do you in your medical monitoring report
23 include a narrative description of this estimate in
24 the Hruday study that speaks to the US population?
25 MR. INSOGNA: Object -- objection to

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1 form.
2 THE WITNESS: Yeah, can you say that
3 again?
4 BY MS. BOGDAN:
5 Q. In your medical monitoring report did you
6 include in the narrative a specific mention to these
7 values in the Hruday study that estimate daily
8 dietary intake of NDMA in the US population?
9 MR. INSOGNA: Same objection.
10 THE WITNESS: Let me look. Yes, I
11 do.
12 BY MS. BOGDAN:
13 Q. And where do you mention this in your
14 medical monitoring report?
15 A. Paragraph 30, "As detailed in my report,
16 estimated dietary intake of NDMA (excluding beer and
17 tobacco) from seven studies yield an average
18 cumulative exposure of," blah, blah, blah. The
19 citation to the seven studies are references 3
20 through 9. Reference 3 is exactly the paper that
21 we're talking about.
22 Q. I asked if in the narrative of your report
23 you specifically mention the values that the Hruday
24 study estimates as the daily dietary intake of US --
25 of NDMA in the US population, which ranges from

<p style="text-align: right;">Page 174</p> <p>1 30 nanograms to 60 nanograms per day, if you 2 actually mention the values in your narrative? 3 MR. INSOGNA: Object to form. 4 THE WITNESS: So of the seven studies 5 that I cite, I do not cite the specific 6 values for any of those individual seven 7 studies. What I cited was the average level 8 from those seven studies, which I consider 9 to be a more reliable number to base an 10 opinion on, but they are included by 11 citation. 12 So if I were to include every number 13 from every paper that I read we would have a 14 10,000-page report. So I'm confident that 15 any scientist or physician reading that 16 statement, can see what it is based on and 17 what studies it refers to and encompasses. 18 BY MS. BOGDAN: 19 Q. This averaging that you did across these 20 seven studies, did you do the figuring on a separate 21 calculation sheet? 22 A. My recollection is I did on an Excel 23 spreadsheet when I was writing my original report 24 back in -- back over the summer. 25 Q. You have a similar spreadsheet like the one</p>	<p style="text-align: right;">Page 176</p> <p>1 purposes of arriving at the numbers, but as I said 2 sitting here right now, I don't recall if there is a 3 spreadsheet or not. 4 Q. If you locate such a spreadsheet I would ask 5 that you continue to maintain it. 6 A. Certainly. 7 Q. If you can go to page -- not page, to 8 paragraph 62 of your medical monitoring report. 9 A. Yes. 10 Q. The second sentence that you have in that 11 paragraph begins, Notwithstanding the above 12 conclusion that seven of the nine claimed cancer 13 associations with NDMA lack reliable scientific 14 support from dietary epidemiological studies. 15 Do you see that? 16 A. Yes, I do. 17 Q. What are the two cancers that you're not 18 referring to in that statement? 19 A. What that statement is referring to is -- 20 since this is specifically in reference to 21 Dr. Madigan's Table 1 and this is also predicated on 22 my very explicit statement in the supplemental 23 report paragraph 47, "Second, for the many reasons 24 described at length in my report, dietary 25 epidemiology studies are an unreliable basis for</p>
<p style="text-align: right;">Page 175</p> <p>1 that was marked, I believe, as Exhibit 18 in the 2 previous deposition -- 3 A. There's nothing that is -- 4 Q. -- calculating -- 5 A. -- that -- I'm sorry, is labeled number 6 what? 7 Q. You said you used the spreadsheet in the 8 previous deposition that was involving your 9 calculations of the different potential exposures 10 from the contaminated valsartan medication. 11 And I'm asking if you have a similar 12 spreadsheet for your averaging of those seven 13 studies to come up with the cumulative exposure 14 average of 4,190 micrograms over a 70-year lifetime, 15 as stated in paragraph 30 of your medical monitoring 16 report? 17 A. Sitting here right now, I don't recall if I 18 had a spreadsheet back in the summer. I believe 19 that I did. Sitting here right now, I can't point 20 to it. There's certainly the exhibit that you're 21 discussing -- yeah, this is labeled in a way that 22 hopefully anyone involved in this litigation can 23 look at it and have it be intuitively obvious. 24 That isn't the way that I would do a 25 spreadsheet or a calculation for myself for the</p>	<p style="text-align: right;">Page 177</p> <p>1 identifying an amount of NDMA or NDEA associated 2 with an increased risk of cancer in human beings." 3 And I raise that because the context of the 4 statement that you just had me read is, of course, 5 encompassed within that original one. I don't 6 accept that any of these numbers, statistically 7 significant or not, are a reliable basis to identify 8 a threshold associated with increased risk. 9 And, in fact your own experts have 10 contradicted themselves and said there is no 11 threshold. But the -- I believe that -- 12 MS. BOGDAN: You can take that down, 13 please. Thank you. I couldn't see you, 14 Dr. Chodos. I had... 15 THE WITNESS: Consider yourself 16 lucky. 17 BY MS. BOGDAN: 18 Q. Well, you know, I consider myself lucky that 19 you can hear me and I can hear you, so... 20 A. Thank goodness for small favors. 21 So the way -- in the discussion in my 22 supplemental report, is I went through the tissue 23 cites that Dr. Madigan refers to. 24 Q. I'm just asking you say "seven of the nine"? 25 A. I know what you're asking me and I'm -- and</p>

<p style="text-align: right;">Page 178</p> <p>1 so the answer is right in my report. So we're 2 starting from nine, so paragraph 53 and following. 3 We're starting with nine cancers of which, 4 basically, seven are addressed by dietary 5 epidemiology studies, okay, three of those seven -- 6 so there's only seven being addressed at all, but 7 three of those seven, bladder cancer, prostate 8 cancer, pancreas cancer, there's no statistically 9 significant increased risk associated with NDMA 10 dietary lifetime cumulative exposures was shown in 11 any study that Dr. Madigan lists. So those three 12 are off the board. So let's take them away. 13 "In addition, for gastric cancer and 14 esophageal cancer, the majority of studies listed by 15 Dr. Madigan did not show a statistically significant 16 increased risk of cancer associated with dietary 17 lifetime cumulative exposure to NDMA (gastric 18 cancer: Five of nine studies not statistically 19 significant; esophageal cancer: Three of four 20 studies not statistically significant.)" 21 And mind you, these are the studies he's 22 referring to, to establish his threshold. There's 23 also -- there's no statistically significant 24 increased risk for liver cancer, even though that's 25 supposed to be the most sensitive cite.</p>	<p style="text-align: right;">Page 180</p> <p>1 and several of which -- that are presented with -- 2 where there are no significant findings. 3 So I think this Table 1 underscores the 4 points made in my supplemental report, I believe. 5 Q. So the two cancers that are not in the seven 6 of the nine claimed are lung and colorectal; is that 7 the answer? 8 A. Of the dietary studies, yes. 9 Q. Okay. Thank you. 10 Did you consider the Song meta-analysis of 11 the gastric studies? 12 A. I have looked at the Song meta-analysis. 13 Q. What is the purpose of the meta-analysis? 14 A. The purpose of the meta-analysis is to 15 attempt to take multiple published studies and to 16 attempt to combine them in some way that increases 17 power without sacrificing validity by combining 18 things that were actually done by different people 19 at different times in different populations using 20 different methods. 21 Q. Increasing the power of a study, in general, 22 is that a positive thing? 23 A. I apologize, but I feel that you didn't -- 24 maybe I didn't make myself clear. 25 So in aggregate, if you have increased power</p>
<p style="text-align: right;">Page 179</p> <p>1 So even when considering only two of the 2 seven cancers that Dr. Madigan evaluated in Table 1, 3 for which at least half of the studies showed a 4 statistically significant association with dietary 5 lifetime cumulative exposure to NDMA, these values 6 ranged from 6,114 to 16,363 micrograms for lung 7 cancer, so an average of 11,238 micrograms, and 8 3,343 to 27,628 micrograms for colon -- colorectal 9 cancer. 10 Q. So the answer to my -- 11 A. So of the table that you present -- 12 Q. Sorry. 13 A. -- of the table that he presents for dietary 14 epidemiology studies the only two for which there's 15 a majority of studies that are statistically 16 significant are lung and colorectal. 17 And as I point out in my report, if I'm 18 looking at 25 studies selected by plaintiffs' expert 19 to make the argument that there is a reliable 20 threshold for lifetime cumulative exposure that 21 could be identified and I see that right from the 22 get-go half of those studies aren't even 23 statistically significant and that there's multiple 24 cancers that either aren't even addressed by dietary 25 epidemiology as in there are no significant findings</p>	<p style="text-align: right;">Page 181</p> <p>1 and everything else stays the same -- if I could 2 have one set of investigators have a -- of 3 essentially a similar population have a much larger 4 number of cases, that might be associated with 5 increased power. 6 But just referring to a meta-analysis as -- 7 well, all it's really doing is increasing power 8 because you're aggregating studies, what my prior 9 answer was trying to get across was that would be a 10 mischaracterization of what a meta-analysis is. 11 So by increasing the number of cases, you 12 are decreasing the accuracy because you are 13 combining things that are dissimilar. 14 Q. If you have -- are combining things that are 15 similar, right, is increasing the power usually a 16 good thing, if there is a homogeneous blending of 17 studies? 18 A. So my accurate answer to you is there is no 19 such thing as either similar or -- you know, every 20 epidemiological study has strengths and limitations. 21 They're performed by different people in different 22 populations using different methods. And I think 23 many people would say that meta-analyses are fraught 24 with problems, for exactly that reason that when you 25 start combining things that were done in very</p>

<p style="text-align: right;">Page 182</p> <p>1 different ways and very different people, very hard 2 to know whether the answer that you get is, you 3 know, accurate, if you will. 4 And, in fact, I was -- well, I'll leave it 5 at that. 6 Q. So in your opinion you don't favor 7 meta-analysis, is that what I'm gleaning from you? 8 A. No, that's not what you're hearing from me 9 and I apologize for not being clear. 10 It's going to depend on the study and the 11 studies that are aggregated and the methods by which 12 it is done, so I can't answer that in the abstract. 13 I've tried to outline for you what some of the 14 potential problems are that one could run into, but 15 I can't answer it in the abstract. 16 Q. Okay. In speaking of the potential 17 problems, were you mentioning those in reference to 18 the Song meta-analysis or just mentioning them in 19 general? 20 A. You -- I lost like the first five or six 21 words of what you said. 22 Q. I said when you were referencing those 23 limitations of a meta-analysis study, were you 24 speaking in terms of the Song meta-analysis study or 25 were you just speaking to meta-analysis studies in</p>	<p style="text-align: right;">Page 184</p> <p>1 gastric cancer and yielded a relative risk, which 2 they said -- they said, "There was, however, 3 considerable between-study heterogeneity LCE's 4 across the component studies ranged from 5 1,412 micrograms to 6,607 micrograms." And then the 6 very next sentence is Dr. Madigan saying "I note 7 that Loh, et al., reported a stomach cancer hazard 8 ratio of 1.13 adding Loh to the Song meta-analysis 9 yields a estimate of 1.32." 10 And so when we talk about the problems with 11 meta-analyses, which is what I'm answering, one of 12 the problems is what studies people choose to 13 include. And the fact that Dr. Madigan decided that 14 he would add one on his own to a published 15 meta-analysis is quite striking to me. 16 Q. That's your analysis of what Dr. Madigan 17 did, which is not what I was asking. 18 What I was asking is if you, one, when I 19 asked the question to begin with, I wasn't sure if 20 you were answering just in general or with regard to 21 your analysis of Song. 22 But what I'm asking is did you, Dr. Chodosh, 23 do your own independent analysis of the Song 24 meta-analysis? 25 A. I did not do an -- and by an "independent</p>
<p style="text-align: right;">Page 183</p> <p>1 general? 2 A. I believe that those -- those would be some 3 of the general potential limitations of 4 meta-analyses. And, again, you would have to look 5 at the individual, the particular meta-analysis and 6 the studies that it was attempting to aggregate 7 where one of those -- you know, yet another of those 8 limitations is which studies do authors decide to 9 include or exclude. 10 And in that respect, if I recall, Dr. 11 Madigan, I believe, takes at least one 12 meta-analysis, possibly two, where he indicates that 13 while the authors -- he noticed that they didn't 14 include a study that he might have thought was 15 interesting and that are -- here. 16 So paragraph 10 of Dr. Madigan's report -- 17 Q. I'm sorry, I'm not -- I'm sorry, Doctor. 18 I'm not asking what Dr. Madigan did. My -- 19 A. No, I'm answering your question. And if I 20 could finish my answer, I would be grateful. 21 Q. Okay, I'll let -- this is -- 22 A. This is literally what you are talking 23 about. Paragraph 9 is the 2015 meta-analysis by 24 Song, et al. that's what we're talking about. 25 Paragraph 9, it included 11 studies concerning NDMA</p>	<p style="text-align: right;">Page 185</p> <p>1 analysis," are you asking me did I try to obtain the 2 raw data from Song et al., and perform a 3 statistic -- a statistical analysis of my own? 4 Q. Or did you look for additional dietary 5 studies as Dr. Madigan did that you would feel would 6 be properly included in that meta-analysis or did 7 you yourself look at the Song meta-analysis and come 8 up with your own critique of its strengths and 9 limitations? 10 MR. INSOGNA: Objection, compound. 11 THE WITNESS: So the meta-analysis by 12 Song is subject to the same types of 13 limitations that I outlined for you as being 14 common limitations of meta-analyses. 15 Fundamentally, given the statement in my 16 report that dietary epidemiology studies 17 fundamentally are not a reliable basis for 18 establishing an LCE associated with human 19 cancer risk. 20 You can aggregate as many as you like 21 and you're still left with the collection of 22 studies that are an unreliable basis to 23 establish a threshold for risk. 24 MR. INSOGNA: Rosemarie, -- 25</p>

<p>Page 186</p> <p>1 BY MS. BOGDAN:</p> <p>2 Q. And that would be your opinion, correct?</p> <p>3 THE WITNESS: I'm sorry, Peg.</p> <p>4 THE COURT REPORTER: Can you repeat</p> <p>5 that question, please, Rosemarie?</p> <p>6 BY MS. BOGDAN:</p> <p>7 Q. I said, and that would be your opinion,</p> <p>8 correct?</p> <p>9 A. Yes, it's a paragraph in a document labeled</p> <p>10 "Opinions of Lewis A. Chodosh, M.D., Ph.D," so, yes,</p> <p>11 I think that's what we're here to talk about is my</p> <p>12 opinions.</p> <p>13 MR. INSOGNA: Rosemarie, when you are</p> <p>14 at a transition point to take a break, a</p> <p>15 short break.</p> <p>16 MS. BOGDAN: Sure. Now would be</p> <p>17 fine. I had just finished with the Song</p> <p>18 meta-analysis unless you would like to hear</p> <p>19 about that some more.</p> <p>20 MR. INSOGNA: You are finished with</p> <p>21 Song?</p> <p>22 MS. BOGDAN: I am finished with Song.</p> <p>23 MR. INSOGNA: Yeah, okay. That's</p> <p>24 what I thought.</p> <p>25 MS. BOGDAN: I'm just saying, we</p>	<p>Page 188</p> <p>1 A. Okay. Hang on. That's which Exhibit?</p> <p>2 Q. It was marked, I believe, as Exhibit 6.</p> <p>3 A. Okay.</p> <p>4 Q. My question is: Were you aware that the FDA</p> <p>5 published an NDMA estimated risk associated with the</p> <p>6 recalled valsartan?</p> <p>7 A. So I am aware and as I recall, you and I</p> <p>8 talked about it to some extent at my last</p> <p>9 deposition.</p> <p>10 Q. Okay. My question is for this medical</p> <p>11 monitoring cause of action, did you compare the FDA</p> <p>12 estimated NDMA additional risk of cancer with the</p> <p>13 risks associated with the plaintiffs' proposed</p> <p>14 medical monitoring plan?</p> <p>15 A. Can you say that again?</p> <p>16 Q. Sure.</p> <p>17 For this medical monitoring cause of action,</p> <p>18 did you do any type of comparison of the FDA's</p> <p>19 estimated NDMA risk, cancer risk, to any cancer</p> <p>20 risks associated with the plaintiffs' proposed</p> <p>21 medical monitoring plan?</p> <p>22 A. Well, so those two things you are</p> <p>23 referencing, the FDA estimate that you are referring</p> <p>24 to says "there may be one additional case of</p> <p>25 cancer," so it doesn't say there will be or there</p>
<p>Page 187</p> <p>1 could all breakout in song, maybe, you know,</p> <p>2 that would take -- but if you would like to</p> <p>3 take a break right now, then that's fine.</p> <p>4 MR. INSOGNA: Thank you. I would</p> <p>5 like to.</p> <p>6 THE WITNESS: I would like to hear</p> <p>7 what the song is.</p> <p>8 THE VIDEOGRAPHER: Off the record at</p> <p>9 3:54.</p> <p>10 (Brief recess.)</p> <p>11 THE VIDEOGRAPHER: We are back on the</p> <p>12 record at 4:06 p.m.</p> <p>13 BY MS. BOGDAN:</p> <p>14 Q. Dr. Chodosh, are you aware that the FDA</p> <p>15 published an NDMA estimated risk with this</p> <p>16 laboratory analysis of valsartan products?</p> <p>17 MR. INSOGNA: Object to form.</p> <p>18 THE WITNESS: You want to point me</p> <p>19 specifically to what your reference is.</p> <p>20 MS. BOGDAN: Could we pull up the</p> <p>21 laboratory analysis of valsartan products</p> <p>22 that was marked as Exhibit 6 today.</p> <p>23 BY MS. BOGDAN:</p> <p>24 Q. And it's, Dr. Chodosh, right on the first</p> <p>25 page of this where it says "NDMA estimated risk"?</p>	<p>Page 189</p> <p>1 would be or we expect there would be. It says</p> <p>2 "there may be," as in it's a possibility, which is</p> <p>3 based on linear low-dose extrapolation.</p> <p>4 And for the plaintiffs, boy, I don't --</p> <p>5 maybe you can point me to some numbers, because I</p> <p>6 read your complaint and it's -- it simply lists a</p> <p>7 certain number of months of duration of exposure to</p> <p>8 APIs from different manufacturers.</p> <p>9 So that was part of what made this quite</p> <p>10 challenging is that I don't see you having committed</p> <p>11 to any numbers or risks.</p> <p>12 Q. I was referring to the risks associated with</p> <p>13 the actual medical treatment that is proposed in the</p> <p>14 medical monitoring plan, the things that we went</p> <p>15 through and -- earlier which were the specialized</p> <p>16 testing, the lab tests, the blood smears, the --</p> <p>17 those things.</p> <p>18 Did you do any type of risk analysis with</p> <p>19 regard to the cancer risk versus the risks to the</p> <p>20 patient of undergoing the monitoring procedures that</p> <p>21 the plaintiffs have put forth in the plan?</p> <p>22 MR. INSOGNA: Objection, vague.</p> <p>23 THE WITNESS: So as a physician in</p> <p>24 reading an estimated -- the FDA estimated</p> <p>25 risk of one in 8,000 people might get</p>

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1 cancer. From first principles as a
2 physician, I would say there's no way that
3 you could justify medical monitoring given
4 that almost 50% of people ultimately develop
5 cancer.
6 So a risk of trying to find the one
7 person in 8,000, if -- that's even assuming
8 it is that, that there isn't a screening
9 program, as a physician, that I understand
10 where you say, Ah, the risk is one in 8,000
11 of cancer, should we go do this procedure?
12 That's me speaking as a physician.
13 As part of my supplemental report,
14 that was not a focus of my opinions, other
15 than I believe my report points out that
16 risks on the order of, you know, one in
17 10,000, one in 100,000, you know, one in
18 100,000 being the 96 nanogram per day, that
19 even if one were to accept that those are
20 actual risks, which I don't believe they
21 are, even if one were to accept that those
22 are actual risks, they are minuscule
23 compared to the risks we all have of getting
24 cancer as one gets older. That's extremely
25 rare, compared to the disease that's

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1 occurring throughout the population, namely
2 cancer.
3 BY MS. BOGDAN:
4 Q. Do you have an opinion with regard to one
5 out of how many number of people risk is necessary
6 to warrant medical monitoring?
7 MR. INSOGNA: Objection to form.
8 THE WITNESS: So I'm not here to
9 opine on at what point -- at what point does
10 risk justify or outweigh the potential harm
11 from specific screening procedures. My
12 opinion as I've laid out is that none of the
13 plaintiffs at the maximum possible
14 hypothetical exposures to NDMA or NDEA would
15 be at an increased risk for cancer.
16 And, therefore, if you have a
17 population that has the same risk, namely
18 people who took these valsartan products
19 have the same risk of cancer as everybody
20 else in the country, that does not warrant
21 medical monitoring.
22 You know, that's my opinion. They're
23 not at increased risk so why would you take
24 on potential harm from the medical
25 monitoring tests that are proposed.

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1 BY MS. BOGDAN:
2 Q. You refer to the language that's highlighted
3 here for NDMA estimated risk, the FDA statement
4 reads, "FDA estimated that if 8,000 people took the
5 highest valsartan dose (320 milligrams) containing
6 NDMA from the recalled batches daily for four years,
7 there may be one additional case of cancer over the
8 lifetimes of the 8,000 people."
9 So they're talking about additional cancer
10 above and beyond the background rate?
11 A. I'm sorry, was that a question? I
12 couldn't -- you cut out for a few words. Was that a
13 question?
14 Q. Right, so I'm just -- do you see in the
15 language from the FDA how they -- how they speak
16 specifically about not there's one case of cancer in
17 8,000 people, but they're referring to there may be
18 one additional case of cancer?
19 A. Oh, yes, I understand that, that's how I was
20 answering that question, that out of those 8,000
21 people over the course of their lifetime nearly
22 4,000 of those people will develop cancer. And what
23 this FDA statement says is instead of 4,000 people
24 getting cancer in their lifetime it might be 4,001
25 with the emphasis on "may be," because the FDA risk

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1 estimate is based on linear low-dose extrapolation
2 as you and I have talked about, and as is written
3 extensively in my report.
4 So that assumes that there is no threshold
5 and that one molecule of NDMA will increase risk,
6 which I think as we've talked about is a ludicrous
7 proposition.
8 Q. Isn't it also true that the FDA is basing
9 that risk assessment on the highest dose of
10 valsartan based upon their testing is
11 20.19 micrograms of NDMA in a 320 tablet?
12 MR. INSOGNA: Objection to form.
13 THE WITNESS: So that's how that
14 sentence reads and given the context in this
15 document laboratory analysis of valsartan
16 products, that's what I assume. [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 So I think it's the same number
23 either way and almost certainly the
24 exposures were substantially less than that
25 just given the realities of the assumptions

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1 that are made.

2 But, of course, the most important

3 assumption in this sentence that you have

4 highlighted is the "may be" and the

5 recognition that this is based on the

6 assumption that there is no threshold

7 because you're dealing with doses that

8 were -- in effect could not be measured in

9 human beings or in animals.

10 BY MS. BOGDAN:

11 Q. Is it your understanding when the NDMA --

12 when FDA did the NDMA estimated risk that it used an

13 average amount of contamination in the tablets or

14 when it does an estimated risk calculation, like the

15 one you see highlighted on the screen, it uses the

16 highest amount found in the tablets?

17 MR. INSOGNA: Objection to form.

18 THE WITNESS: It -- as it stated

19 there, it used the highest amount and your

20 question was -- to me was, do I recognize

21 that that was the highest amount that the

22 FDA measured with the implication being that

23 there are other measurements that might be

24 higher.

25 And my point was that the average of

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1 the other measurements that you showed me,

2 as I'm sitting here trying to recall that

3 table, was just about that same level as

4 what the FDA measured and based this risk

5 estimate on.

6 BY MS. BOGDAN:

7 Q. Yes. [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 MR. INSOGNA: Objection to form.

12 THE WITNESS: So the difference

13 between -- that you're not within, you know,

14 several thousandfold of the dose that would

15 be needed to cause cancer or the doses of

16 endogenous exposure that we all have,

17 whether that's 3,000 or 1,000 doesn't

18 matter, you're still far below any threshold

19 where you would expect to see any increase

20 in risk.

21 And I think a calculation, if talking

22 about is it that 4,000 people will get

23 cancer or will 4,001 people get cancer

24 emphasizes that this is, even with their --

25 the FDA's conservative assumptions, which

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1 are intended for regulatory purposes for

2 precautionary reasons, that even by that

3 measure it is a very small risk.

4 But I do not -- as I have articulated

5 in my report, I do not believe that there is

6 any increased risk at all and nor is the FDA

7 stating that there is.

8 BY MS. BOGDAN:

9 Q. Let's move on to some of the studies that

10 you cited in your medical monitoring report

11 regarding endogenous formation of NDMA.

12 MS. BOGDAN: Can we pull up, I almost

13 hate to say, the Tricker study, "Urinary

14 excretion of nitrite, nitrate."

15 TRIAL TECHNICIAN: Counsel, do you

16 have a number assigned to that one?

17 MS. BOGDAN: I'm looking at my cheat

18 sheet with regard to the numbers. Just a

19 second. Let me see if I can locate it.

20 It's called "Urinary excretion of nitrite,

21 nitrate and N-nitroso compounds."

22 TRIAL TECHNICIAN: I have two Tricker

23 studies and neither one of those contains

24 those words in the title.

25 MS. BOGDAN: Okay. Let me run to

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1 another study. How about Tricker

2 Spiegelhalder urinary excretion, you

3 don't -- that's the one you can't find,

4 right?

5 How about Tricker, "N-nitroso

6 compounds and man"?

7 TRIAL TECHNICIAN: Yes, coming up.

8 MS. BOGDAN: Thank you.

9 BY MS. BOGDAN:

10 Q. Dr. Chodosh, this is one of the references

11 that you cite in your medical monitoring report?

12 A. I don't have it yet.

13 Q. Okay. Sorry.

14 (Document marked for identification

15 as Chodosh Deposition Exhibit No. 16.)

16 TRIAL TECHNICIAN: You should now see

17 Exhibit 16 if you hit refresh.

18 THE WITNESS: Okay. Thank you.

19 Okay. I see the paper.

20 BY MS. BOGDAN:

21 Q. That paper is speaking of endogenous

22 formation of N-nitrosamines, in general, correct?

23 A. Well, I see both exogenous -- it's dealing

24 with exogenous and endogenous.

25 Q. But it's dealing with N-nitrosamines as a

<p style="text-align: right;">Page 198</p> <p>1 group, correct, not NDMA?</p> <p>2 A. That's correct. Well, I mean, they're</p> <p>3 certainly talking about NDMA. They're also talking</p> <p>4 more broadly about N-nitrosamines.</p> <p>5 MS. BOGDAN: If we could pull up the</p> <p>6 Jakszyn study.</p> <p>7 THE WITNESS: Are we -- I'm sorry,</p> <p>8 are we done with this study?</p> <p>9 MS. BOGDAN: We're done.</p> <p>10 THE WITNESS: Study, yeah.</p> <p>11 TRIAL TECHNICIAN: I'm sorry, was</p> <p>12 that Jaiswal, J-A-I-S-W-A-L?</p> <p>13 MS. BOGDAN: No. It was Jakszyn,</p> <p>14 J-A-K-S-Z-Y-N.</p> <p>15 TRIAL TECHNICIAN: Sorry, I don't</p> <p>16 have anything with Jakszyn.</p> <p>17 Is there more to the title?</p> <p>18 MS. BOGDAN: It's J-A-K-S-Z-Y-N, you</p> <p>19 don't have that?</p> <p>20 TRIAL TECHNICIAN: No, I'm sorry.</p> <p>21 MS. BOGDAN: Okay.</p> <p>22 How about Holtrop, H-O-L-T-R-O-P.</p> <p>23 It's called "Diet composition is associated</p> <p>24 with endogenous formation."</p> <p>25 TRIAL TECHNICIAN: No, I'm sorry.</p>	<p style="text-align: right;">Page 200</p> <p>1 Q. I believe it is. I think it's the --</p> <p>2 A. If you can -- I mean, the paper is familiar.</p> <p>3 I can't remember where specifically it's referenced.</p> <p>4 Can you point me to where it's referenced?</p> <p>5 Q. Yes, I believe it's your reference number</p> <p>6 12.</p> <p>7 A. And is there a paragraph with my</p> <p>8 supplemental report? And I'm happy to look for it,</p> <p>9 but if you know what the paragraph is...</p> <p>10 Q. I believe it's paragraph 34, where you</p> <p>11 string cite and it's one of the studies that you</p> <p>12 have after the sentence that reads, "Indeed, NDMA</p> <p>13 and other nitrosamines are formed endogenously</p> <p>14 within the body as a consequence of normal human</p> <p>15 physiology." And you cite to reference three and</p> <p>16 then 11 through 16 and this reference is number 12.</p> <p>17 And I was just going to ask you a general</p> <p>18 question as to why you referenced this particular</p> <p>19 study, which is focused on bladder cancer patients</p> <p>20 that have -- I don't know how you pronounce this</p> <p>21 condition, schistosomiasis.</p> <p>22 A. Schistosomiasis.</p> <p>23 Q. Schistosomiasis?</p> <p>24 A. Correct.</p> <p>25 Q. Did I do it better the second time.</p>
<p style="text-align: right;">Page 199</p> <p>1 MS. BOGDAN: Okay. Why don't we</p> <p>2 just -- I think there are some documents</p> <p>3 that might have gotten stuck in hyperspace</p> <p>4 here, so I've just run into a series of them</p> <p>5 now that aren't in the portal. So let's</p> <p>6 just take a three-minute break and I can see</p> <p>7 if something didn't quite upload, okay.</p> <p>8 THE VIDEOGRAPHER: Off the record at</p> <p>9 4:26.</p> <p>10 (Brief recess.)</p> <p>11 THE VIDEOGRAPHER: We are back on the</p> <p>12 record at 4:32 p.m.</p> <p>13 MS. BOGDAN: Which study did you say,</p> <p>14 Mike, that you had identified that you can</p> <p>15 put up?</p> <p>16 TRIAL TECHNICIAN: I will mark</p> <p>17 Tricker as Exhibit 17.</p> <p>18 (Document marked for identification</p> <p>19 as Chodosh Deposition Exhibit No. 17.)</p> <p>20 MS. BOGDAN: Which Tricker? We'll</p> <p>21 see.</p> <p>22 BY MS. BOGDAN:</p> <p>23 Q. Is this one of the studies, Doctor, that you</p> <p>24 cited in your medical monitoring report?</p> <p>25 A. Hang on, yeah.</p>	<p style="text-align: right;">Page 201</p> <p>1 A. Perfect.</p> <p>2 Q. What is schistosomiasis?</p> <p>3 A. Schistosomiasis is a parasitic disease and</p> <p>4 it's very common in certain parts of the world</p> <p>5 caused by trematodes.</p> <p>6 Q. Is that something that's common here in the</p> <p>7 US? I've never heard of it.</p> <p>8 A. Schistosomiasis in the United States would</p> <p>9 typically -- would be one of the things that medical</p> <p>10 students read about and get tested about and are</p> <p>11 unlikely to see unless they were in a tertiary</p> <p>12 academic medical center. Endemic in other parts of</p> <p>13 the world, not in the United States.</p> <p>14 Q. Sounds like the medical equivalent of the</p> <p>15 rule against perpetuities.</p> <p>16 A. Okay. I have more than that so...</p> <p>17 Q. Does the cite to this just show that there</p> <p>18 could be physiological conditions that happen in the</p> <p>19 human body that influence endogenous formation of</p> <p>20 nitrosamines?</p> <p>21 A. I think what it's saying is that since</p> <p>22 there's a control group in this paper that people</p> <p>23 make -- you know, there are endogenous amounts of</p> <p>24 NDMA that get excreted in the urine.</p> <p>25 Q. And you are referring to the control group,</p>

<p style="text-align: right;">Page 202</p> <p>1 not the group that has this infectious condition?</p> <p>2 A. Well, for -- for instance, if one looks at</p> <p>3 Table 2, the heading "Concentrations microgram per</p> <p>4 day of volatile nitrosamines in urines," there are</p> <p>5 German controls that has NDMA levels of .2. There</p> <p>6 are Egyptian controls that have an average level</p> <p>7 that's like a .27 and then you have patients who</p> <p>8 have schistosomiasis.</p> <p>9 Q. Which have higher levels, correct?</p> <p>10 A. Yes, associated with that infection, that's</p> <p>11 correct.</p> <p>12 MS. BOGDAN: Well, now maybe we will</p> <p>13 have success in pulling up the Jakszyn</p> <p>14 paper, J-A-K-S-Z-Y-N.</p> <p>15 TRIAL TECHNICIAN: This will be</p> <p>16 Exhibit 18. It's available on the link and</p> <p>17 I will have it on your screen momentarily.</p> <p>18 MS. BOGDAN: And this is cited in</p> <p>19 your medical monitoring report as reference</p> <p>20 Number 13.</p> <p>21 (Document marked for identification</p> <p>22 as Chodosh Deposition Exhibit No. 18.)</p> <p>23 BY MS. BOGDAN:</p> <p>24 Q. Which, again, is in that same paragraph</p> <p>25 number 34.</p>	<p style="text-align: right;">Page 204</p> <p>1 Q. All right. My overarching question,</p> <p>2 Dr. Chodosh, is just does this study provide any</p> <p>3 estimate of the endogenous formation of NDMA?</p> <p>4 A. So, in general, NDMA is the most abundant of</p> <p>5 nitrosamines, so they're N-nitrosamines. And the</p> <p>6 point of the paper is that endogenous nitrosamines</p> <p>7 formation is about 100 times greater than NDMA</p> <p>8 exposure from the diet and that the cancer risk</p> <p>9 association in the stomach does not correlate with</p> <p>10 NDMA intake, it correlates with endogenous</p> <p>11 nitrosamines, arguing that it is endogenous</p> <p>12 N-nitrosamines, which are more important in</p> <p>13 determining cancer risk and not NDMA exposures, in</p> <p>14 this case, that would be dietary exposures.</p> <p>15 Q. How many compounds are there in the</p> <p>16 nitrosamine family?</p> <p>17 A. There are -- my recollection -- I can't</p> <p>18 remember whether it's 100 or -- there are a broad</p> <p>19 number of N-nitrosamines of which NDMA is -- in the</p> <p>20 setting of diet, my understanding is, is one of the</p> <p>21 more abundant, if not the most abundant. It's</p> <p>22 certainly the best studied of N-nitrosamines.</p> <p>23 Q. Are the N-nitrosamines in the family equally</p> <p>24 genotoxic?</p> <p>25 A. I'm sorry, you cut out right at the</p>
<p style="text-align: right;">Page 203</p> <p>1 A. One second. Yes, that's correct.</p> <p>2 TRIAL TECHNICIAN: Rosemarie, for the</p> <p>3 record, I just wanted to let you that</p> <p>4 Bob Kum from Duane Morris also just joined</p> <p>5 us in the room now.</p> <p>6 MS. BOGDAN: Okay. Bob from</p> <p>7 Duane Morris.</p> <p>8 BY MS. BOGDAN:</p> <p>9 Q. Now, this study is focused on N-nitroso</p> <p>10 compounds, in general, correct?</p> <p>11 A. That's correct.</p> <p>12 Q. Does this study estimate an amount of</p> <p>13 endogenous NDMA that forms, as opposed to</p> <p>14 nitrosamines in general?</p> <p>15 A. If you look at Table 1, there is --</p> <p>16 endogenous nitrosamines is listed and NDMA is listed</p> <p>17 as a standalone below it and then if you look at</p> <p>18 Table 2 --</p> <p>19 Q. Well, let me just ask a question about</p> <p>20 Table 1.</p> <p>21 Is the NDMA listed, though, in Table 1, the</p> <p>22 NDMA that someone would get exogenously from diet or</p> <p>23 air or water?</p> <p>24 A. Give me a moment. I need to check back.</p> <p>25 (Witness reviews document.)</p>	<p style="text-align: right;">Page 205</p> <p>1 beginning.</p> <p>2 Q. I'll ask it a different way.</p> <p>3 Are there varying degrees of potency of the</p> <p>4 various compounds that are in the N-nitrosamines</p> <p>5 group?</p> <p>6 A. Yeah, so potency is a chemical compound</p> <p>7 specific analysis. And my recollection is ten or</p> <p>8 15 percent of N-nitrosamines are not considered be</p> <p>9 to be carcinogenic when tested in animals, so there</p> <p>10 clearly is variability across the family, as you</p> <p>11 would expect, given that they each have different</p> <p>12 chemical structures.</p> <p>13 MS. BOGDAN: If we could pull up the</p> <p>14 Holtrop study, H-O-L-T-R-O-P.</p> <p>15 (Document marked for identification</p> <p>16 as Chodosh Deposition Exhibit No. 19.)</p> <p>17 BY MS. BOGDAN:</p> <p>18 Q. Now, this study is another one that you</p> <p>19 specifically reference in your medical monitoring</p> <p>20 report as reference number 15.</p> <p>21 A. If you could just give me a moment to</p> <p>22 refresh my memory.</p> <p>23 Q. Sure.</p> <p>24 A. (Witness reviews document.)</p> <p>25 Q. Which, again, is footnoted in paragraph 34.</p>

<p style="text-align: right;">Page 206</p> <p>1 A. Okay.</p> <p>2 Q. And asking the same question again, is this</p> <p>3 a study of endogenous formation of N-nitroso</p> <p>4 compounds in general, meaning the whole group, as</p> <p>5 opposed to NDMA specifically?</p> <p>6 A. Give me one moment.</p> <p>7 (Witness reviews document.)</p> <p>8 So I believe that this is N-nitroso</p> <p>9 compounds in general. Although, again, my</p> <p>10 understanding is that NDMA is typically the most</p> <p>11 abundant in that class of endogenous N-nitrosamines.</p> <p>12 Q. Turning your attention to page 1657 of this</p> <p>13 study, directing your attention to the left-hand</p> <p>14 side of that paragraph which reads, "The ultimate</p> <p>15 link between diet, endogenously formed NOC, and</p> <p>16 causation and prevention of DNA damage in animals</p> <p>17 and humans is still missing."</p> <p>18 A. Let me just read this paragraph for context</p> <p>19 so I can try to get a better idea what they're</p> <p>20 talking about.</p> <p>21 Q. That was going to be my question, do you</p> <p>22 have an understanding of what the authors are</p> <p>23 talking about?</p> <p>24 A. (Witness reviews document.)</p> <p>25 So if I look at the sentence immediately</p>	<p style="text-align: right;">Page 208</p> <p>1 linked to NOC formation." I think they're looking</p> <p>2 at the effects of diet composition and in particular</p> <p>3 of protein composition and how that is related to</p> <p>4 endogenous NOC formation.</p> <p>5 So it's the same thing in my report, in both</p> <p>6 of my reports. And the same thing that was</p> <p>7 basically in Jakszyn that red meat in particular is</p> <p>8 a known source of NDMA and endogenous nitrosamines.</p> <p>9 Q. But this study, again, is looking at NOCs,</p> <p>10 nitrosamines in general, correct?</p> <p>11 A. Yes, that's correct.</p> <p>12 MS. BOGDAN: If we could pull up the</p> <p>13 Vermeer study, V-E-R-M-E-E-R.</p> <p>14 (Document marked for identification</p> <p>15 as Chodosh Deposition Exhibit No. 20.)</p> <p>16 BY MS. BOGDAN:</p> <p>17 Q. And this is reference number 14 in your</p> <p>18 medical monitoring report.</p> <p>19 TRIAL TECHNICIAN: This will be</p> <p>20 Exhibit 20. It's available through the</p> <p>21 marked exhibit link and will be up on your</p> <p>22 screen momentarily.</p> <p>23 THE WITNESS: And if I could just</p> <p>24 have one second to refresh my memory.</p> <p>25 (Witness reviews document.)</p>
<p style="text-align: right;">Page 207</p> <p>1 preceding the one you asked me about, which is a</p> <p>2 summation sentence, it says, "Even though NOC" --</p> <p>3 nitrosamines compounds -- "even though NOC</p> <p>4 concentrations were not determined in these studies,</p> <p>5 they provide a cause of the DNA adducts that are</p> <p>6 specific to DNA methylating agents such as NOC. The</p> <p>7 ultimate link between diet, endogenously formed NOC,</p> <p>8 and causation and prevention of DNA damage to humans</p> <p>9 and animals is still missing."</p> <p>10 My interpretation, given that this is in a</p> <p>11 discussion and based on context, is they're saying,</p> <p>12 in fact, there is endogenous DNA damage and the</p> <p>13 formation of promutagenic DNA adducts and that that</p> <p>14 is higher in the setting of a high protein or a high</p> <p>15 red meat diet. So as in endogenous causes of</p> <p>16 nitrosamine formation damaging DNA is, you know, a</p> <p>17 major issue, for lack of a better phrase, and that</p> <p>18 that last sentence essentially says, we haven't</p> <p>19 figured out every last thing. We don't know every</p> <p>20 piece of the puzzle.</p> <p>21 Q. And they're looking for basically a link</p> <p>22 between red meat intake and endogenous NOCs,</p> <p>23 correct?</p> <p>24 A. Well, as it says in the abstract, "Red meat</p> <p>25 is considered the most important dietary component</p>	<p style="text-align: right;">Page 209</p> <p>1 Okay.</p> <p>2 BY MS. BOGDAN:</p> <p>3 Q. The purpose of this study was to look at</p> <p>4 NDMA formation with a high amine rich diet, correct?</p> <p>5 A. From my reading it looks like that is at</p> <p>6 least one -- [Zoom glitch].</p> <p>7 MS. BOGDAN: Oh, the audio cut out.</p> <p>8 Oh, please tell me that the audio is</p> <p>9 working, please. It's not working?</p> <p>10 THE VIDEOGRAPHER: Excuse me, Doctor,</p> <p>11 can you hear me? Mr. Insogna, can you hear</p> <p>12 me?</p> <p>13 Going off the record at 4:54.</p> <p>14 (Brief recess.)</p> <p>15 THE VIDEOGRAPHER: We are back on the</p> <p>16 record at 4:58.</p> <p>17 BY MS. BOGDAN:</p> <p>18 Q. So, Doctor, before we lost the audio, I</p> <p>19 believe, I was asking you if the purpose of the</p> <p>20 Vermeer study is to look at nitrosamine formation</p> <p>21 associated with amine rich diets? And they use</p> <p>22 different types of fish in the study to study that</p> <p>23 phenomenon.</p> <p>24 A. Well, it's looking at intake of nitrate and</p> <p>25 what the impact might be on endogenous</p>

<p>Page 210</p> <p>1 N-nitrosamines and it's in the setting of as in 2 combination with an amine rich diet. 3 But they're each variables that are being 4 tested here, both the nitrate and the amines. 5 Q. And the nitrate without the amines, how is 6 that impacting NDMA formation? 7 A. When you say "without the amines," I don't 8 understand what you mean. 9 Q. They test the nitrate as a control without 10 the amine rich foods as well? 11 A. Which part of this study are you referring 12 to because you can't get rid of amines in food 13 unless there are no proteins whatsoever. 14 Q. Right. I'm asking you if they just tried 15 nitrate rich foods alone without any type of protein 16 or if the nitrate that you're referring to was 17 always being put on board, so to speak, with the 18 amine rich? 19 A. Yeah, I don't -- my memory of this paper is 20 not so detailed that I recall that immediately 21 evident to me, looking at it, what the -- if you 22 will, what the baseline diet is. But, right, pretty 23 much -- I mean, all diets are going to have some 24 protein in it, which means that there's going to be 25 amines in it.</p>	<p>Page 212</p> <p>1 of volatile nitrosamines formed in the stomach are 2 probably much higher than the amounts excreted in 3 urine," and then it refers to Spiegelhalter and 4 co-workers showing that between 0.5 and 2.4% of an 5 ingested NDMA dose is excreted or metabolized in 6 urine. 7 Or less than 0.5 in the absence of alcohol, 8 so that's actually -- that's an important number 9 because that comes into play in Hrudey and a number 10 of other things. 11 But then in the next sentence it says 12 "Assuming that 0.5% of the NDMA is excreted in 13 urine, the volunteers in this study may have formed 14 174 micrograms of NDMA per day or 2.9 micrograms per 15 kilogram body weight per day during days 1-3 of the 16 test week." 17 And they're making the point of how does 18 that compare with carcinogenic doses in the rat. 19 And, yeah, granted this is what, 1990 something, but 20 this is one of the estimates of endogenous NDMA 21 production. I reference that actually in the table 22 that we were talking about because this is -- this 23 is the low end of the estimate, so for completeness 24 I included this endogenous estimate, whereas the 25 Hrudey estimates were six, seven, eight, nine times</p>
<p>Page 211</p> <p>1 So they're saying there's no such thing -- 2 you're not able to do a study or I don't think this 3 is a study of what's the effect of nitrate in the 4 absence of any amines, but I would have to spend 5 more time with the paper to refresh my memory about 6 the details. 7 Q. What was your purpose in citing it in your 8 medical monitoring report as a reference? 9 A. Well, so, currently you can get at it from 10 the first sentence so "Formation of nitrites from 11 ingested nitrate, can result in several adverse 12 health effects and implies a genotoxic risk as an 13 consequence of endogenous formation of carcinogenic 14 N-nitroso compounds." 15 So partly this is another piece of the 16 puzzle that arrives at the conclusion that 17 endogenous formation of N-nitrosamines is -- is 18 biologically important and then this is also, as I 19 recall, this was the body of data that were also 20 employed to make estimates or one of the estimates 21 of endogenous formation of NDMA. 22 But, again, I'd have to go back through this 23 paper. It's a pretty detailed paper, but -- so it 24 says -- go to page 462, to the far column on the 25 right, to the paragraph that begins "Absolute levels</p>	<p>Page 213</p> <p>1 higher than this. And I did calculations, as you 2 may recall, that looked both at the levels of 3 endogenous NDMA production predicted by this paper 4 and the levels of endogenous production estimated -- 5 I should say "estimated" not "predicted" -- 6 estimated by Hrudey, et al., by two of the three 7 methods that they used, each of which makes the same 8 point that these levels of endogenous production of 9 NDMA that have been estimated are substantially 10 higher than what is generally accepted as amounts in 11 the diet. That is, amounts of pre-formed NDMA in 12 the diet. 13 And, of course, if one were to accept -- I 14 believe, you were making the point that while the -- 15 Hrudey gave an estimate for the United States 16 population of preformed NDMA dietary intake. Well, 17 in fact, that would just mean that the endogenous 18 formation is an even greater multiple of what's in 19 the diet. They all make the same point that 20 endogenous NDMA production, endogenous 21 N-nitrosamines production, that's the thing driving 22 the biology. That's the endogenous mutagen or one 23 of the endogenous mutagens, I should say. 24 Q. In the case of the contaminated valsartan 25 with NDMA or NDEA, each patient that is taking</p>

<p style="text-align: right;">Page 214</p> <p>1 valsartan would have a background amount of NDMA 2 exposure in their diet, correct? And the amount in 3 the contaminated medication would be in addition to 4 their background? 5 A. Yes, in a medication, if there's NDMA in a 6 medication, that will be added to whatever NDMA is 7 in the diet. 8 But the point of these papers that you're 9 citing -- that your -- we're talking about right now 10 are that those amounts are quite low compared to 11 endogenous production of NDMA and, therefore, the 12 DNA repair systems that have evolved to repair that 13 specific type of DNA damage caused by that, that's 14 the point of these. 15 MS. BOGDAN: If you could please pull 16 up the next exhibit, the Krul study, 17 K-R-U-L. 18 (Document marked for identification 19 as Chodosh Deposition Exhibit No. 21.) 20 BY MS. BOGDAN: 21 Q. This study, Dr. Chodosh, is in your amended 22 list of materials considered that was provided to 23 our office with the medical monitoring. 24 A. Yes, may I have a moment to refresh my 25 memory.</p>	<p style="text-align: right;">Page 216</p> <p>1 looking at dynamic changes as best I can refresh my 2 memory, as a function of time and as a function of 3 how nitrites are added. But I think as has been 4 apparent in recent publications of both Bronstein 5 and Gau [ph.], that the conditions in which such 6 experiments are done have a dramatic influence on 7 what the results are, number one. And that, number 8 two, things that authors describe as "physiological" 9 very often are not. 10 So I would have to spend more time with this 11 to actually see what are the -- what are the ranges 12 here, especially of nitrite and how those 13 correspond. 14 Q. From the abstract, assuming that there's a 15 hyphen between the 2.3 and the 422 and the 1.8 and 16 the 42.7, the study indicates that there could be a 17 wide range, right, of NDMA forming under the 18 conditions in the study, correct? 19 A. Well, that's -- so, yes, but that's circular 20 and it may be that -- in that wide range that none 21 of it overlaps with what happens with human beings. 22 That's my point. 23 Q. Right, I get it. I get it. 24 A. In their in vitro system that they have set 25 up that's what they're reporting and the real</p>
<p style="text-align: right;">Page 215</p> <p>1 Q. Sure. 2 A. (Witness reviews document.) 3 Q. The question I'm going to ask you, Doctor, 4 is in the abstract itself. 5 A. Okay. Why don't you ask it and then I'll 6 see if I can answer it based on -- about this paper. 7 Q. In the abstract, does the study indicate 8 that under these conditions the cumulative amounts 9 of NDMA formed were 2.3 to 422 micrograms of NDMA 10 and 1.8 to 42.7 micrograms of NDMA at a rapid and 11 slow gastric PH decrease respectively? 12 A. I -- two things, one, I don't see a hyphen 13 there. I see "2.3" and then I see a space and I see 14 "422." So with that paper, I don't -- that isn't 15 how I would write a range. 16 Is it -- do you see it there? 17 Q. There is a hyphen on the paper copy I'm 18 looking at. I'm thinking that happened in the 19 upload and the translation on to the screen. I 20 don't see it on the screen, but the one that I have 21 has the hyphen there between the 2.3 and the 422 and 22 between the 1.8 and the 42.7? 23 A. Yeah. And, I guess, the overall point is 24 really this is -- this is an in vitro model of 25 simulated conditions in the stomach where they're</p>	<p style="text-align: right;">Page 217</p> <p>1 question, of course, is how good a model is this for 2 what happens in human beings. 3 Q. Turning to page to 53 of the study, which is 4 the third page. 5 A. I'm sorry, which page? 6 Q. Page 53 and in the study right before 7 "Materials and Methods"? 8 A. Yeah. 9 Q. They're indicating that "Experiments with 10 respect to the inhibition of NDMA formation were 11 formed with two inhibitors, orange juice as a source 12 of ascorbic acid and black tea, which contains large 13 amounts of polyphenols"? 14 A. Yes, I see where you read that. 15 Q. Do you know those to be inhibitors of NDMA 16 formation? 17 A. As a general matter or at specific 18 concentrations and specific context? 19 Q. As a general matter. 20 A. I don't know as a general matter. As a 21 biochemist, basically, I would believe has to be on 22 the concentration of either of those components and 23 the overall conditions of the experiment like PH and 24 everything else that's present. And, in fact, just 25 scanning through this on the next page, page 54 on</p>

<p style="text-align: right;">Page 218</p> <p>1 the right-hand column it says "To investigate 2 whether the formation of NDMA can occur under the 3 experimental conditions of the in vitro model. The 4 gastric compartment was loaded with 300 milliliters 5 of 0.1 molar setting citrate buffer (pH 6.8) 6 containing 5-millimolar DMA and 5-millimolar sodium 7 nitrite." 8 Q. Yeah, I understand, Doctor, that you would 9 want to look at the study further to determine the 10 different -- 11 A. I'm sorry, I wasn't done. 12 What my point is, 5-millimolar study of 13 nitrite is to my recollection wildly 14 nonphysiological. So this is back to the original 15 point that I made that people -- if you're modeling 16 something in vitro, it's critical that you're 17 actually modeling something that has physiological 18 conditions and just looking at that one number, 19 that's not vague. 20 To the best of my recollection, I believe 21 that number is multiples, many multiples of 22 physiological, of the upper range of physiological. 23 I could be wrong, but that's my best recollection. 24 Q. Not to interrupt you, Dr. Chodosh, but my 25 question right now on the table had to do with</p>	<p style="text-align: right;">Page 220</p> <p>1 I... 2 THE WITNESS: I have it back. Okay. 3 MS. BOGDAN: Okay. 4 THE WITNESS: Is this 22? 5 TRIAL TECHNICIAN: That's correct. 6 This is Exhibit 22. 7 BY MS. BOGDAN: 8 Q. Doctor, and you're familiar with this study 9 as it's cited to in your report? 10 A. Yes. 11 Q. And directing your attention to the 12 participants. This was a study that involved 5,150 13 Danish patients with no history of cancer, correct, 14 aged 40 years or older using valsartan at the 1st of 15 January 2012, or initiating use between the 1st of 16 January 2012, and the 30th of June 2017, correct? 17 A. Yes, you read that correctly. 18 Q. And this study was actually ended on 19 June 30th, 2018. 20 Do you see that? 21 A. Yes. 22 Q. And there were actually various recalls of 23 valsartan that occurred after this study closed. 24 Are you aware of that? 25 A. Yes.</p>
<p style="text-align: right;">Page 219</p> <p>1 whether or not orange juice and black tea can 2 inhibit NDMA formation, that's the last question I 3 asked you. 4 A. I answered you. I said as a biochemist that 5 has got to be dependent on the concentration of each 6 of the components of the system. That's the answer 7 to your question. 8 Q. Okay. 9 MS. BOGDAN: Let's pull up Pottegard, 10 please. 11 MR. INSOGNA: You lost your exhibits 12 window. 13 THE WITNESS: I lost my exhibits 14 window. 15 (Document marked for identification 16 as Chodosh Deposition Exhibit No. 22.) 17 BY MS. BOGDAN: 18 Q. Doctor, this is another one of the studies 19 that you specifically cited as a reference in your 20 medical monitoring report. 21 MR. INSOGNA: Rosemarie, one second. 22 Dr. Chodosh lost the exhibits window. We're 23 just reopening that right now. 24 MS. BOGDAN: Okay. I don't have much 25 more, but with the different drops like that</p>	<p style="text-align: right;">Page 221</p> <p>1 Q. Would you consider that to be a limitation 2 of the study that the full extent of the 3 contaminated medication wasn't known at the time 4 that the study period closed? 5 A. Say that again, please. 6 Q. Would you consider that to be a limitation 7 of the study, in that the full amount of the 8 contaminated valsartan wasn't known as of the time 9 the study closed, which would prevent proper 10 identification of patients that had taken 11 contaminated valsartan versus not contaminated 12 valsartan? 13 MR. INSOGNA: Objection to form. 14 THE WITNESS: I don't think I'm 15 following your logic. I apologize, maybe 16 it's just late in the day. But I see where 17 it says when the end of the study period 18 was, 30 June 2018, and I know that there 19 were additional recalls that happened later 20 that year, at the end of that year, but I'm 21 not -- I'm not following what your argument 22 is. 23 BY MS. BOGDAN: 24 Q. Okay. There's a "Conclusion" section on 25 that first page of the study?</p>

<p style="text-align: right;">Page 222</p> <p>1 A. Yes.</p> <p>2 Q. It mentions that "The results do not imply a</p> <p>3 markedly increased short term overall risk of cancer</p> <p>4 in users of valsartan contaminated with NDMA.</p> <p>5 However, uncertainty persists about single cancer</p> <p>6 outcomes and studies with longer follow-up are</p> <p>7 needed to assess long term cancer risk."</p> <p>8 Do you see that conclusion?</p> <p>9 A. I see where you've read that and you've read</p> <p>10 it correctly.</p> <p>11 Q. Okay. What was the follow-up period for</p> <p>12 this study, do you know?</p> <p>13 A. (Witness reviews document.)</p> <p>14 It says "Participants were followed until</p> <p>15 cancer outcome, death, migration or end of the study</p> <p>16 period, whichever occurred first." But I'm looking</p> <p>17 for what the overall follow-up time was.</p> <p>18 Q. I direct you to the "Results" section on</p> <p>19 page 3.</p> <p>20 A. It says "A median of 4.6 years of follow-up</p> <p>21 interquartile range 2.0-5.5 years."</p> <p>22 Q. Would you consider only having a median of</p> <p>23 4.6 years of follow-up in a study with a cancer</p> <p>24 endpoint to be a limitation of the study?</p> <p>25 A. Well, yes and no. The -- what's notable to</p>	<p style="text-align: right;">Page 224</p> <p>1 follow people who have been exposed to valsartan</p> <p>2 products in that period of time for as long as you</p> <p>3 want. The point is that their exposures are so far</p> <p>4 below any dose that could conceivably cause cancer</p> <p>5 you're going to get the same result.</p> <p>6 But you can't have it both ways. You can't</p> <p>7 both claim that valsartan exposure causes cancer in</p> <p>8 the short term and at the very same time turn around</p> <p>9 and say, Oh, but you would never see it unless you</p> <p>10 looked at very long intervals of time. It's just</p> <p>11 internally contradictory, like much of the evidence</p> <p>12 that your experts have presented.</p> <p>13 MS. BOGDAN: Let's move to the Gomm</p> <p>14 study, please, G-O-M-M.</p> <p>15 (Document marked for identification</p> <p>16 as Chodosh Deposition Exhibit No. 23.)</p> <p>17 BY MS. BOGDAN:</p> <p>18 Q. And this is another one of the studies that</p> <p>19 you cited in your references to your medical</p> <p>20 monitoring report?</p> <p>21 A. That's correct. Since these were -- well --</p> <p>22 Q. Yes?</p> <p>23 A. -- I believe these are studies of</p> <p>24 populations exposed to product at issue in this</p> <p>25 litigation so that they're perfectly ignored.</p>
<p style="text-align: right;">Page 223</p> <p>1 me about this study is that this time frame</p> <p>2 corresponds quite closely to what your experts have</p> <p>3 claimed that NDMA can cause cancer in human beings.</p> <p>4 So while I believe that opinion,</p> <p>5 particularly from Dr. Panigraphy, is utterly</p> <p>6 unsupported by available scientific evidence and, in</p> <p>7 fact, contradicted by a battleship of medical and</p> <p>8 scientific evidence. It's the plaintiffs who have</p> <p>9 claimed that cancers can arise within this general</p> <p>10 period of time and people exposed to valsartan</p> <p>11 products containing NDMA or NDEA.</p> <p>12 So to some extent this is -- well, this</p> <p>13 would be a logical test of your expert's predictions</p> <p>14 and it says their predictions are wrong.</p> <p>15 Q. I'm asking if you consider a 4.6 follow-up</p> <p>16 period for a study with cancer as the endpoint a</p> <p>17 sufficient period of time?</p> <p>18 MR. INSOGNA: Objection to form.</p> <p>19 THE WITNESS: A sufficient period of</p> <p>20 what?</p> <p>21 BY MS. BOGDAN:</p> <p>22 Q. Can you see that as a limitation of the</p> <p>23 study?</p> <p>24 A. In general, longer follow-up is better for</p> <p>25 cancer outcomes. However, in this case, you could</p>	<p style="text-align: right;">Page 225</p> <p>1 Q. And in the Gomm study a statistically</p> <p>2 significant association was found between exposure</p> <p>3 to NDMA contaminated valsartan and hepatic cancer;</p> <p>4 isn't that correct?</p> <p>5 A. You've read the conclusion correctly.</p> <p>6 However, as I believe I noted in my -- in both of my</p> <p>7 reports that there was no dose response effect for</p> <p>8 the liver as would be expected and that the multiple</p> <p>9 testing adjustment was not made and so the absence</p> <p>10 of those two things -- I do not put a great deal of</p> <p>11 weight on that particular finding.</p> <p>12 And, in fact, the study that we just looked</p> <p>13 in Pottgard, I don't think they saw any liver</p> <p>14 cancer so that's -- for first principles you have a</p> <p>15 marginal -- at best a marginal association that was</p> <p>16 not seen in another study so that is sort of the</p> <p>17 opposite of a robust or a consistent finding, so I</p> <p>18 put very little weight on that.</p> <p>19 Q. But the authors of the Gomm study did find a</p> <p>20 statistically significant association between</p> <p>21 exposure to NDMA-contaminated valsartan and hepatic</p> <p>22 cancer, correct?</p> <p>23 A. As it says it's associated with a slightly</p> <p>24 increased risk of hepatic cancer, no association</p> <p>25 with risk of cancer overall. And as I've said, it</p>

<p>Page 226</p> <p>1 may have been nominally marginally significant, but 2 the fact that, to my recollection, was not adjusted 3 overall in the study and the fact that there's no 4 dose response and the fact that another study of 5 patients exposed to the same products there's no 6 liver cancer that tells me this is not a consistent 7 finding. 8 Q. All right. 9 If you could please look at the results on 10 the first page of the study and it says on the 11 results "A total of 780,871 persons who had filed a 12 prescription for valsartan between 2012 and 2017 13 were included in the study," correct? 14 A. Correct. 15 Q. And that would make this a larger study size 16 than the Pottegard study, correct? 17 A. Larger does not mean better. 18 Q. I didn't ask better, I asked if it was 19 larger? 20 A. I don't recall what the number was in 21 Pottegard. 22 Q. The number in Pottegard was 5,150 Danish 23 patients. The Pottegard had 5,150 patients and this 24 study had 780,000-plus patients and then the results 25 read as follows: "There was no association between</p>	<p>Page 228</p> <p>1 Q. On the very first page of the study, Doctor, 2 under the summary? 3 A. Okay, so not in the "Results" section in the 4 "Results" section of the summary. Okay. 5 Q. Right, that's right. 6 So I'll ask my question one more time since 7 now we're oriented to where I was reading from. 8 The last sentence of the "Results" section 9 in the summary of the study reads, "A statistically 10 significant association was found, however, between 11 exposure to NDMA-contaminated valsartan and hepatic 12 cancer"; isn't that true? 13 A. You read those words correctly. And so, for 14 instance, it also says in this paper, "We cannot 15 rule out residual confounding." 16 Q. Oh. 17 A. So, for instance, they did not adjust for 18 factors that might have influenced risk factors for 19 liver cancer. And this drug is being given to a 20 population of people with hypertension, in general, 21 who to my understanding of liver cancer risk factors 22 are going to have an increased risk of liver cancer. 23 So when you have findings that are not 24 adjusted for multiple testing, do not show a dose 25 response, are very close to 1.0 and have not been</p>
<p>Page 227</p> <p>1 the exposure to NDMA-contaminated valsartan and the 2 overall risk of cancer" -- 3 A. I'm sorry, where are you reading? 4 Q. I'm reading from -- 5 A. Is that the beginning of the "Results" 6 section or where is that? Okay, got it. 7 Q. That is in the "Results" section. I first 8 read -- I'm reading the whole section. 9 A. Yes, just -- years are not accessible so I 10 just have a little icon of a table, but I can't 11 actually see that table. 12 Q. I'm sorry, and the audio isn't great either. 13 But my last question is does the "Results" 14 section say in the final sentence in the "Results" 15 section "A statistically significant association was 16 found, however, between exposure to 17 NDMA-contaminated valsartan and hepatic cancer"? 18 A. I'm sorry, where are you reading? 19 Q. I read the last sentence of the "Results" 20 section? 21 MR. INSOGNA: On the first page. 22 THE WITNESS: I'm looking at the end 23 of the "Results" section and that isn't the 24 end of the "Results" section, so... 25 BY MS. BOGDAN:</p>	<p>Page 229</p> <p>1 adjusted for risk factors for the disease, that 2 is -- in my opinion, that's extraordinarily weak 3 evidence. 4 Q. And from your -- 5 MS. BOGDAN: You can pull that down. 6 BY MS. BOGDAN: 7 Q. With regard to the contamination of -- 8 contaminated valsartan, do the higher milligram 9 doses of valsartan always have a higher amount of 10 NDMA compared to the lower doses of valsartan or 11 does it vary by manufacturer, different lots, 12 et cetera? 13 A. It varies by manufacturer and by different 14 lots. 15 MS. BOGDAN: Those are all the 16 questions I have. 17 MR. INSOGNA: Rosemarie, I will have 18 some follow-up questions. I'm anticipating 19 they will be pretty limited. I would like 20 to take maybe ten minutes to look through my 21 notes and get that together. 22 THE VIDEOGRAPHER: Off the record at 23 5:36. 24 (Brief recess.) 25 THE VIDEOGRAPHER: We are back on the</p>

<p style="text-align: right;">Page 230</p> <p>1 record at 5:53. 2 BY MR. INSOGNA: 3 Q. All right. Dr. Chodosh, I appreciate you 4 bearing with us today. I have just a few follow-up 5 questions based on Counsel's questions as to earlier 6 today. 7 The first question for you, did you read the 8 plaintiffs' medical monitoring complaint in this 9 case? 10 A. Yes, I did. 11 Q. And did you read their memorandum of law in 12 support of their motion to certify a class for 13 medical monitoring? 14 A. Yes, I did. 15 Q. In those documents, did you see a reference 16 to a specific numerical lifetime cumulative exposure 17 threshold for NDMA or NDEA that would qualify a 18 plaintiff for membership in their proposed class? 19 A. No, I did not. The algorithm appears to be 20 predicated entirely on how many months of a 21 particular manufacturer's product one took. There 22 are no numbers in there that would translate to an 23 NDMA/NDEA level. 24 Q. And is that an opinion that you have set 25 forth in your report in this case?</p>	<p style="text-align: right;">Page 232</p> <p>1 bit higher, it's irrelevant because on a ratio basis 2 they're tiny compared to endogenous production and 3 the levels needed to generate cancer. 4 And the second point I just have to 5 underscore is the language of those papers is 6 talking about NDMA levels, but in none of those 7 papers, to my knowledge, are NDMA levels ever 8 measured in the food that any participant, was 9 exposed to in any of these studies. These are 10 estimates based on, you know, old food tables, so 11 they're not even measuring the thing that is -- they 12 are attempting to associate with a cancer outcome. 13 Q. And I think I understand your point there 14 about the measuring in the dietary studies. 15 Just so our record is clear, what is the 16 significance to your opinions about that lack of 17 measuring of NDMA levels in food? 18 A. So if you don't actually measure the NDMA 19 levels in the food that participants took you can't 20 possibly know what their exposures actually were. 21 You're estimating based on, you know, a series of 22 food charts and self-reported eating behaviors and 23 lots of things that are notoriously unreliable. 24 And in addition to that, there are thousands 25 of things in the food not being measured, so dietary</p>
<p style="text-align: right;">Page 231</p> <p>1 A. Yes, it is. It's set forth in my opinion 2 that there is no way to go from that algorithm to 3 determine a specific exposure of a plaintiff to NDMA 4 or NDEA. 5 Q. And in the sections of your supplemental 6 report that discuss those opinions about that 7 algorithm, have you set forth the basis for your 8 opinions and the details surrounding those opinions? 9 A. Yes, I have. 10 Q. Earlier today Counsel asked you a number of 11 questions about studies of dietary exposure to NDMA. 12 Do you generally recall that questioning? 13 A. Yes, I do. 14 Q. Does dietary exposure to NDMA or NDEA factor 15 into the opinions that you've offered in this case? 16 A. It factors into from the standpoint that I'm 17 trying to factor in all the information that I can 18 get. So from that standpoint, yes, but the critical 19 aspect or the two critical aspects of diet are that 20 the estimates of dietary intake are minuscule 21 compared to endogenous exposures and are minuscule 22 compared to the lowest dose that has ever been shown 23 to cause cancer in any animal. 24 So whether those dietary levels that are 25 estimated of NDMA are a little bit lower or a little</p>	<p style="text-align: right;">Page 233</p> <p>1 studies are infamously subject to all sorts of 2 inaccuracy. And that's just one of the reasons why, 3 as set forth in my report, they are an unreliable 4 basis to determine a threshold for increased risk 5 due to exposure to NDMA. 6 Q. Now, a few responses ago or maybe your prior 7 response, you mentioned that on a ratio basis the 8 levels estimated in these dietary studies are 9 minuscule compared to endogenous NDMA formation. 10 Is there also set forth in your report an 11 opinion about the ratio basis of potential exposure 12 to NDMA or NDEA through valsartan and endogenous 13 production? 14 A. Yes, there are opinions in my report and it 15 is similar to diet. They are very low exposures 16 compared to endogenous exposures to NDMA and 17 certainly -- well, compared to the lowest possible 18 dose of NDMA that could cause cancer in laboratory 19 animals. 20 Q. And just so I make sure that I'm clear on 21 that. 22 The level of potential exposure to NDMA or 23 NDEA through valsartan is are you saying lower -- 24 you tell me, as compared against endogenous and then 25 also as compared against the lowest level shown to</p>

<p>Page 234</p> <p>1 cause any cancer in any mammal species.</p> <p>2 A. So endogenous levels of NDMA production as</p> <p>3 it has been estimated are up to a thousand times</p> <p>4 higher than the levels of likely exposure to</p> <p>5 plaintiffs who took valsartan products that might</p> <p>6 have had NDMA or NDEA and they are -- and the level</p> <p>7 of NDMA exposure required to generate cancers in an</p> <p>8 animal are even higher than the endogenous levels.</p> <p>9 So there's just an enormous gulf between the</p> <p>10 lowest dose of NDMA that would cause cancer in even</p> <p>11 the most sensitive animal and the greatest amount of</p> <p>12 NDMA or NDEA that a plaintiff could have been</p> <p>13 exposed to as a consequence of taking valsartan</p> <p>14 products.</p> <p>15 Q. Okay, I understand that. Thank you.</p> <p>16 I'm going to go back to something that we</p> <p>17 talked about very early in the day, so forgive me.</p> <p>18 But Counsel asked you whether you were</p> <p>19 offering any opinions about whether any of the</p> <p>20 specific tests in plaintiffs' medical monitoring</p> <p>21 plan were appropriate for people who are at risk of</p> <p>22 cancer.</p> <p>23 Do you remember generally those questions?</p> <p>24 A. I do.</p> <p>25 Q. Okay. So, first, let me ask you, are you</p>	<p>Page 236</p> <p>1 involves?</p> <p>2 A. Yes, I do have an opinion.</p> <p>3 Q. What is that opinion?</p> <p>4 A. They should not.</p> <p>5 Q. Okay. And why is that?</p> <p>6 A. Because for the many reasons articulated in</p> <p>7 my original report and my supplemental report the</p> <p>8 exposures are far, far too low to conceivably</p> <p>9 elevate risk for cancer. So the risk of cancer of</p> <p>10 the population of people who took valsartan products</p> <p>11 during this period of time, is effectively the same</p> <p>12 risk of cancer as everybody else in the country.</p> <p>13 So if you're not elevated risk compared to</p> <p>14 other people, then you get no benefit from some</p> <p>15 additional kind of screening. And what you get is</p> <p>16 the additional risk of harm that comes from doing</p> <p>17 screening procedures that basically are not</p> <p>18 indicated in this population.</p> <p>19 Q. Okay. And I understand that was sort of an</p> <p>20 encapsulation of your report.</p> <p>21 Are those opinions that you just summarized</p> <p>22 for us set forth in detail in your original and</p> <p>23 supplemental reports in this litigation?</p> <p>24 A. Yes, they are.</p> <p>25 Q. And do you set forth each of the bases for</p>
<p>Page 235</p> <p>1 aware whether there are cancer-screening protocols</p> <p>2 in place for the general population of Americans?</p> <p>3 A. There are screening protocols that are</p> <p>4 recommended for people that -- as implemented by</p> <p>5 physicians talking to their patients, yes.</p> <p>6 Q. Now, Counsel's questions were about whether</p> <p>7 specific tests were appropriate for people who are</p> <p>8 at risk of cancer.</p> <p>9 Let me ask you, generally speaking, who is</p> <p>10 at risk of cancer?</p> <p>11 A. All human beings are at risk of cancer.</p> <p>12 Q. And over the course of a lifetime, what is</p> <p>13 the cancer risk in the general population?</p> <p>14 A. A lifetime cancer risk in this country</p> <p>15 approaches one out of two people.</p> <p>16 Q. Now, when you were answering those questions</p> <p>17 about the specific tests and testing protocol put</p> <p>18 forth by plaintiffs, did I understand correctly that</p> <p>19 you're not offering any opinions about whether any</p> <p>20 specific test would be appropriate for any plaintiff</p> <p>21 in this litigation?</p> <p>22 A. That's correct.</p> <p>23 Q. Do you have any opinion about whether any of</p> <p>24 the plaintiffs should undergo any screening program</p> <p>25 regardless of which tests the proposed program</p>	<p>Page 237</p> <p>1 each of the opinions that you offered in your</p> <p>2 report?</p> <p>3 A. Yes, I do.</p> <p>4 Q. And do you identify the sources that you</p> <p>5 considered in forming those opinions?</p> <p>6 A. Yes, I did.</p> <p>7 MR. INSOGNA: I don't have any</p> <p>8 further questions subject to anything that</p> <p>9 Counsel may ask you.</p> <p>10 BY MS. BOGDAN:</p> <p>11 Q. So you cite extensively in your medical</p> <p>12 monitoring report to the Liteplo 2002 study about</p> <p>13 N-Nitrosodimethylamine, correct?</p> <p>14 MR. INSOGNA: I'm going to object.</p> <p>15 That's beyond the scope of what I just asked</p> <p>16 him about.</p> <p>17 BY MS. BOGDAN:</p> <p>18 Q. Well, I'm going to get right to it then.</p> <p>19 You just testified on redirect regarding the</p> <p>20 scaling of doses of NDMA between animals and humans,</p> <p>21 right, are you aware that the Liteplo study which</p> <p>22 you cite extensively in your report reads "Scaling</p> <p>23 for variations in the ratio of surface area to body</p> <p>24 weight between rodent species and humans was not</p> <p>25 considered appropriate for the measures of exposure</p>

<p>Page 238</p> <p>1 response developed on the basis of experimental data</p> <p>2 in animals, since it is highly probable that the</p> <p>3 carcinogenicity of NDMA is mediated primarily</p> <p>4 through the generation of an active metabolite,</p> <p>5 i.e., the methyldiazonium ion."</p> <p>6 MR. INSOGNA: So --</p> <p>7 BY MS. BOGDAN:</p> <p>8 Q. Are you aware that that study says that?</p> <p>9 MR. INSOGNA: I'm going to make the</p> <p>10 same objection and just point out that you</p> <p>11 asked him extensively about what's in the</p> <p>12 Liteplo or Liteplo study and this is not</p> <p>13 something that I covered in my redirect and</p> <p>14 it's something that you certainly could have</p> <p>15 asked him about before. I won't instruct</p> <p>16 Dr. Chodosh not to answer, though.</p> <p>17 THE WITNESS: I'm happy to answer it</p> <p>18 because you made my point for me, so thank</p> <p>19 you very much.</p> <p>20 I did not do any scaling based on</p> <p>21 surface area. So the very statement that</p> <p>22 you read that says "Scaling by surface area</p> <p>23 is not appropriate," I didn't scale by</p> <p>24 surface area. I scaled by weight, which is</p> <p>25 exactly what the FDA does and exactly what</p> <p>Page 239</p> <p>1 EMA does and exactly what Health Canada</p> <p>2 does, so you've made my point for me, thank</p> <p>3 you.</p> <p>4 BY MS. BOGDAN:</p> <p>5 Q. You scaled between the weight of the rodent</p> <p>6 and the weight of a person, correct?</p> <p>7 A. Milligrams --</p> <p>8 MR. INSOGNA: Same objections.</p> <p>9 THE WITNESS: Milligrams per</p> <p>10 kilogram, that is not surface area.</p> <p>11 BY MS. BOGDAN:</p> <p>12 Q. The species scale between a rodent and a</p> <p>13 human, correct?</p> <p>14 A. I didn't hear the question. Could you</p> <p>15 repeat it?</p> <p>16 Q. You scaled between a rodent and a human,</p> <p>17 correct?</p> <p>18 A. I scaled between a rodent and human as we've</p> <p>19 talked about many times, both now and in September,</p> <p>20 based on milligram per kilogram exposure which is,</p> <p>21 number one, exactly what the FDA does and the risk</p> <p>22 assessment that you showed to me, as well as EMA, as</p> <p>23 well as Health Canada.</p> <p>24 And I did not use a surface area scaling</p> <p>25 factor, which is what you just read what Liteplo</p>	<p>Page 240</p> <p>1 says is inappropriate. And I agree, it's not what I</p> <p>2 did, so please don't mischaracterize what I did.</p> <p>3 MS. BOGDAN: The study speaks for</p> <p>4 itself, but I don't have any further</p> <p>5 questions.</p> <p>6 MR. INSOGNA: I don't either.</p> <p>7 THE VIDEOGRAPHER: Okay. Hearing no</p> <p>8 further questions, that concludes today's</p> <p>9 deposition and the time is 6:08 p.m.</p> <p>10 (Witness excused.)</p> <p>11 ---</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p> <p>Page 241</p> <p>1 C E R T I F I C A T I O N</p> <p>2 I, MARGARET M. REIHL, a</p> <p>3 Registered Professional Reporter, Certified</p> <p>4 Realtime Reporter, Certified Court Reporter,</p> <p>5 Certified LiveNote Reporter, do hereby</p> <p>6 certify that the foregoing is a true and</p> <p>7 accurate transcript of the testimony as</p> <p>8 taken stenographically, by and before me,</p> <p>9 remotely, via Zoom, to the best of my</p> <p>10 ability, and on the date hereinbefore set</p> <p>11 forth.</p> <p>12 I DO FURTHER CERTIFY that I am</p> <p>13 neither a relative nor employee nor attorney</p> <p>14 nor counsel of any of the parties to this</p> <p>15 action, and that I am neither a relative nor</p> <p>16 employee of such attorney or counsel, and</p> <p>17 that I am not financially interested in the</p> <p>18 action.</p> <p>19</p> <p>20</p> <p>21 -----</p> <p>22 Margaret M. Reihl, RPR, CRR, CLR</p> <p>23 CCR License #XI01497</p> <p>24 NCRA License #047425</p> <p>25</p>
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ACKNOWLEDGMENT OF DEPONENT

I, LEWIS A. CHODOSH, M.D., Ph.D., do hereby certify that I have read the foregoing pages and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

LEWIS A. CHODOSH, M.D., Ph.D. DATE

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Exhibit 209

REDACTED

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF NEW JERSEY

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4 IN RE: VALSARTAN, LOSARTAN,
AND IRBESARTAN PRODUCTS MDL No. 2875
5 LIABILITY LITIGATION

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THIS DOCUMENT APPLIES TO ALL HON ROBERT B.
7 CASES KUGLER

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- CONFIDENTIAL INFORMATION -
SUBJECT TO PROTECTIVE ORDER

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<p style="text-align: right;">Page 10</p> <p>1 PROCEEDINGS</p> <p>2</p> <p>3 THE VIDEOGRAPHER: We are now</p> <p>4 on the record. My name is Alex</p> <p>5 Jandrow, I'm a videographer for Golkow</p> <p>6 Litigation Services.</p> <p>7 Today's date is March 10, 2022,</p> <p>8 and the time is 9:19 a.m.</p> <p>9 This video deposition is being</p> <p>10 held in Duane Morris LLP of Boston</p> <p>11 Massachusetts in the matter of</p> <p>12 Valsartan, Losartan, and Irbesartan</p> <p>13 Products Liability Litigation, MDL</p> <p>14 Number 2875, for the United States</p> <p>15 District Court, District of New</p> <p>16 Jersey.</p> <p>17 The deponent is Punam Keller,</p> <p>18 MD.</p> <p>19 And the court reporter is</p> <p>20 Maureen O'Connor Pollard.</p> <p>21 Counsel will now introduce</p> <p>22 themselves for the record.</p> <p>23 MR. DAVIS: John Davis and</p> <p>24 Ruben Honik for the plaintiffs.</p>	<p style="text-align: right;">Page 12</p> <p>1 Q. Okay. Let me start just with</p> <p>2 some background questions for you.</p> <p>3 When were you engaged as an</p> <p>4 expert in this case?</p> <p>5 A. In -- at the end of last year.</p> <p>6 Q. Okay. So November, December?</p> <p>7 A. Yes, that period.</p> <p>8 Q. Okay. Have you given testimony</p> <p>9 under oath before?</p> <p>10 A. Yes.</p> <p>11 Q. Okay. About how many times?</p> <p>12 A. Three, including this one.</p> <p>13 Q. Okay. So two prior times.</p> <p>14 Would that have been in the</p> <p>15 capacity as an expert witness?</p> <p>16 A. Yes.</p> <p>17 Q. Your CV, I believe, lists two</p> <p>18 Johnson & Johnson pelvic mesh cases. Is that</p> <p>19 what you're referring to for your past</p> <p>20 testimony?</p> <p>21 A. Yes.</p> <p>22 Q. Okay. Have you offered an</p> <p>23 expert report in a case where you have not</p> <p>24 been deposed under oath?</p>
<p style="text-align: right;">Page 11</p> <p>1 MR. GOLDBERG: Seth Goldberg on</p> <p>2 behalf of the ZHP defendants and</p> <p>3 defendants.</p> <p>4 MR. SMOLIJ: Alek Smolij on</p> <p>5 behalf of the ZHP defendants.</p> <p>6 MS. ANDRAS: Tiffany Andras on</p> <p>7 behalf of Teva and Actavis</p> <p>8 Pharmaceuticals.</p> <p>9 MR. DAVIS: Good morning,</p> <p>10 Dr. Keller. How are you today?</p> <p>11 ///</p> <p>12 PUNAM ANAND KELLER, Ph.D.,</p> <p>13 having been duly identified and sworn, was</p> <p>14 examined and testified as follows:</p> <p>15 ///</p> <p>16 THE WITNESS: And the first</p> <p>17 thing I want to do is, it's not MD,</p> <p>18 it's Ph.D.</p> <p>19 EXAMINATION</p> <p>20 BY MR. DAVIS:</p> <p>21 Q. Okay. Let me try that again.</p> <p>22 Good morning, Dr. Keller. How</p> <p>23 are you this morning?</p> <p>24 A. Good. How are you?</p>	<p style="text-align: right;">Page 13</p> <p>1 A. Yes.</p> <p>2 Q. About how many times?</p> <p>3 A. Three.</p> <p>4 Q. Okay. And the -- going back to</p> <p>5 the J&J pelvic mesh cases, on whose behalf</p> <p>6 did you submit an expert report?</p> <p>7 A. Defendants.</p> <p>8 Q. That would be the Johnson &</p> <p>9 Johnson defendants?</p> <p>10 A. Johnson & Johnson/Ethicon.</p> <p>11 Q. Which is a subsidiary of</p> <p>12 Johnson & Johnson?</p> <p>13 A. Yes.</p> <p>14 Q. To the best of your</p> <p>15 recollection, what did those expert opinions</p> <p>16 relate to?</p> <p>17 A. They related to my expertise on</p> <p>18 consumer decision-making.</p> <p>19 Q. In the context of evaluating</p> <p>20 Ethicon/J&J's marketing of their pelvic mesh</p> <p>21 products?</p> <p>22 A. Could you repeat that question?</p> <p>23 Q. Sure.</p> <p>24 Would that have been in the</p>

<p style="text-align: right;">Page 14</p> <p>1 context of J&J and Ethicon's marketing and 2 promotion of their pelvic mesh products? 3 A. Could you be more specific? 4 Q. Well, sure. 5 Why don't you tell me what 6 your -- what you were evaluating from a 7 consumer decision-making standpoint regarding 8 Ethicon's pelvic mesh products. 9 A. I was providing opinions on how 10 consumers -- the range of consumer responses 11 to Ethicon's marketing communication for the 12 pelvic mesh. 13 Q. You mentioned Ethicon's 14 marketing communications. Can you describe 15 to me what those included? 16 A. It's been a while. So to the 17 best of my recollection, it was brochures, 18 and I don't remember anything else. 19 Q. Okay. Brochures like the 20 product labeling, or handouts to physicians? 21 A. I don't recall. 22 Q. Okay. Did you do any kind of 23 empirical study, like a survey, in that case? 24 A. That was not my -- no, that was</p>	<p style="text-align: right;">Page 16</p> <p>1 walk me through briefly your educational 2 background, if you don't mind. 3 A. I have a bachelor's in -- from 4 -- it used to be called Bombay University, 5 because that was the name of the city, it's 6 now been changed to Mumbai, but it was first 7 Bombay University. And I majored in 8 economics and statistics, and -- major in 9 economics, minor in statistics. 10 And then I got an MBA with a 11 major in marketing also from Bombay. The 12 name of the school also has been changed a 13 little bit, but it used to be called, in 14 short, JBIMS. 15 And then I came to get a Ph.D 16 in marketing from Northwestern University in 17 the Kellogg school of management. 18 Q. Thank you. 19 So your postgraduate degrees, 20 meaning your MBA and Ph.D, those are in the 21 field of marketing? 22 A. Yes. 23 Q. Okay. 24 A. I'd like to just add with, my</p>
<p style="text-align: right;">Page 15</p> <p>1 not my task. 2 Q. Okay. Have you ever done a 3 damages analysis as an expert in a 4 litigation? 5 A. Define what you mean by 6 "analysis." 7 Q. Have you ever been tasked, for 8 example, with calculating the amount of 9 litigation damages in a case? 10 A. No. 11 Q. Okay. Have you -- I believe 12 you may have answered this indirectly, but 13 you said you did not do a survey or other 14 empirical study of any kind in the J&J case. 15 Have you ever done a survey or empirical 16 study of any kind in litigation in an expert 17 capacity at all? 18 A. No. 19 Q. Okay. Have you ever conducted 20 a survey or some other kind of empirical 21 study outside the context of litigation? 22 A. Yes, frequently. 23 Q. Frequently. 24 Okay. Describe for me, just</p>	<p style="text-align: right;">Page 17</p> <p>1 specialization is consumer behavior. 2 Q. Okay. I've seen that variously 3 referred to as consumer psychology. Similar 4 concept? 5 A. Yes. 6 Q. Okay. Did you go straight to 7 academia after obtaining your postgraduate 8 degrees? 9 A. Yes. 10 Q. Okay. Walk me through just 11 very briefly that history, if you don't mind, 12 and conclude with what you're doing 13 currently. 14 A. I -- upon graduation from the 15 Ph.D program, I have held marketing positions 16 in multiple institutions. 17 Do you need a list of all the 18 institutions? 19 Q. I don't believe so, but let me 20 clarify. 21 You said "marketing positions." 22 You mean like faculty? 23 A. Yes, I was a marketing 24 professor.</p>

<p style="text-align: right;">Page 18</p> <p>1 Q. Marketing professors.</p> <p>2 Okay. And you're currently a</p> <p>3 professor of marketing at Dartmouth?</p> <p>4 A. At the Tuck School of Business</p> <p>5 at Dartmouth.</p> <p>6 Q. Do you teach undergrad or</p> <p>7 graduate students there?</p> <p>8 A. Both.</p> <p>9 Q. Both. Okay.</p> <p>10 All marketing classes?</p> <p>11 A. All related to marketing.</p> <p>12 Q. Okay. My next question was</p> <p>13 what's your research focus, but I believe you</p> <p>14 answered that by telling me it's consumer</p> <p>15 behavior and consumer psychology. Is that</p> <p>16 how you would describe your research focus?</p> <p>17 A. That would be the broadest</p> <p>18 description. A more specific description</p> <p>19 would be with an emphasis on how consumers</p> <p>20 process information, form attitudes and</p> <p>21 beliefs, intentions to purchase, and purchase</p> <p>22 products and services. And the two contexts</p> <p>23 that I study are health and financial</p> <p>24 well-being.</p>	<p style="text-align: right;">Page 20</p> <p>1 there. Did you draft that and provide that</p> <p>2 to them?</p> <p>3 A. I don't recall.</p> <p>4 Q. Okay. But you did say you</p> <p>5 approved the content, I suppose, right?</p> <p>6 A. Yes.</p> <p>7 Q. Okay. It says that "Professor</p> <p>8 Keller is an expert in consumer information</p> <p>9 processing and choice behavior. She studies</p> <p>10 the application of social marketing</p> <p>11 principles and behavioral theory in consumer</p> <p>12 and employee contexts, with a focus on</p> <p>13 designing and implementing consumer</p> <p>14 communication programs."</p> <p>15 Did I read that correctly?</p> <p>16 A. Yes.</p> <p>17 Q. Do you agree with that</p> <p>18 description of your expertise?</p> <p>19 A. It's a subset of my expertise,</p> <p>20 yes.</p> <p>21 Q. When you say "a subset," what</p> <p>22 do you mean by that?</p> <p>23 A. I just shared, you know, I have</p> <p>24 broad expertise that goes beyond how</p>
<p style="text-align: right;">Page 19</p> <p>1 MR. DAVIS: Okay. I'm going to</p> <p>2 mark Keller Exhibit 1, which I'm</p> <p>3 handing to the reporter.</p> <p>4 A. Thank you.</p> <p>5 (Whereupon, Keller Exhibit</p> <p>6 Number 1 was marked for</p> <p>7 identification.)</p> <p>8 BY MR. DAVIS:</p> <p>9 Q. Do you recognize that as a web</p> <p>10 bio for you, Dr. Keller, from the Analysis</p> <p>11 Group website?</p> <p>12 A. I have actually not seen this</p> <p>13 on the website before, but, okay.</p> <p>14 Q. So your testimony is you've</p> <p>15 never seen this bio for you that's on the</p> <p>16 Analysis Group website?</p> <p>17 A. No, I didn't say that. I know</p> <p>18 that they sought approval for putting my bio</p> <p>19 on their website, and they asked me for some</p> <p>20 information, and my recall is that I approved</p> <p>21 it. But I didn't actually see it on the</p> <p>22 website.</p> <p>23 Q. Okay. So under -- there's a</p> <p>24 paragraph under "Summary of Experience"</p>	<p style="text-align: right;">Page 21</p> <p>1 consumers process information. It also</p> <p>2 includes how consumers form attitudes and</p> <p>3 beliefs, intentions to purchase, and purchase</p> <p>4 behavior of products and services.</p> <p>5 Q. Okay. So this -- you would say</p> <p>6 that this description that I just read you</p> <p>7 from your Analysis Group bio would be sort of</p> <p>8 a subset, as you say, of your broader</p> <p>9 expertise in the field of consumer behavior?</p> <p>10 A. Yes. I view it as a summary.</p> <p>11 Like any summary bio, it is not going to be</p> <p>12 exhaustive.</p> <p>13 Q. Have you ever taught an</p> <p>14 economics class, Dr. Keller?</p> <p>15 A. No.</p> <p>16 Q. Do you have any postgraduate</p> <p>17 degrees in economics?</p> <p>18 A. No.</p> <p>19 Q. Do you research in the field of</p> <p>20 economics?</p> <p>21 A. Please be more specific.</p> <p>22 Q. Well, does any of your</p> <p>23 research -- would you characterize any of the</p> <p>24 research that you've done or publications</p>

<p style="text-align: right;">Page 22</p> <p>1 that you've authored, have they been in the 2 field of economics? 3 A. Yes, in the field of behavioral 4 economics. 5 Q. Explain what you mean by 6 "behavioral economics." 7 A. So -- and I'm going to try to 8 simplify things, and just for the purposes of 9 comparison. 10 By no means do I want to say 11 that what I'm saying is an exhaustive 12 description of both fields because that would 13 take us many, many days. 14 From my point of view, and many 15 others, economics -- when economists, or in 16 the field of economics, when they study 17 consumers they use utility theory, and the 18 field of behavioral economics was formed 19 because utility theory was inadequate to 20 explain consumer behavior. 21 To the best of my recollection, 22 there are at least four Nobel Prize winners 23 in the four economic sciences, the Nobel 24 Prize in economic sciences that work on</p>	<p style="text-align: right;">Page 24</p> <p>1 sociology, economics, and anthropology. 2 Q. Can you think of any other 3 journals, or is that the one? 4 A. So Journal of Consumer 5 Psychology is similar. Many of the journals 6 are multidisciplinary, and so it's hard for 7 me to separate the disciplines. 8 Q. You said that there were 9 multiple subdisciplines, for example, for the 10 Journal of Consumer Research. Was your -- 11 and I think you said you were an area editor? 12 A. Correct. 13 Q. Okay. What do you mean by 14 "area editor"? 15 A. So the review process varies 16 for different journals, but a common review 17 process is when a paper is submitted for 18 review for possible publication in the 19 journal, the editor works with the area 20 editor to determine who those reviewers will 21 be, and after the reviews are -- after the 22 reviews do their peer reviews, the area 23 editor gets all of the reviews and makes a 24 recommendation to the editor for the</p>
<p style="text-align: right;">Page 23</p> <p>1 behavioral economics. 2 Q. Okay. But I guess if I'm 3 understanding you correctly, and keeping it 4 high level, when you say "behavioral 5 economics," you're still -- that still falls 6 within the field of consumer behavior, 7 correct? 8 A. It is, and beyond. So I have 9 co-authors that are behavioral economists 10 that are in the economics department. 11 Q. But your focus would be on the 12 behavioral aspect of it, correct? 13 A. In large part, yes. 14 Q. Okay. Are you on any review 15 boards, editorial boards, or do you have any 16 peer-review duties for any economics-related 17 journal? 18 A. Yes. And I want to give you an 19 example. The Journal of Consumer Research, 20 for which in the past I was an area editor, 21 which is even higher than an editorial board 22 member, and have been on the editorial board 23 for many years until recently, is made up of 24 multiple subdisciplines such as psychology,</p>	<p style="text-align: right;">Page 25</p> <p>1 progression of that manuscript for maybe a 2 revision, rejection, acceptance, etcetera. 3 Q. So by "area editor," is that by 4 -- sort of by discipline? "Area" means sort 5 of discipline, and you would assign out -- 6 you would, as the area editor, say you got a 7 manuscript in, you would review the 8 manuscript and say, Oh, well, this pertains 9 mostly to the psychological subdiscipline, so 10 I'm going to send it over to this particular 11 reviewer? Is that sort of how it works? 12 A. It's quite close, yes. 13 Q. Okay. 14 A. You try to find reviewers who 15 are experts in the subject matter of the 16 article -- sorry, of the paper, not an 17 article yet, so that they can provide an 18 expert opinion. 19 Q. Okay. So as the area editor, 20 you would not have been doing the peer 21 reviewing yourself, you would have been 22 assigning it out to peer reviewers based on 23 their area of expertise? 24 A. I write a separate report, and</p>

<p style="text-align: right;">Page 26</p> <p>1 that also in that report includes my own 2 review of the article. And it's, I would 3 say, similar to what I would do as a reviewer 4 on the editorial review board. 5 Q. Okay. Putting aside your 6 behavioral economics, you wouldn't hold 7 yourself out as an expert in economic theory, 8 would you? 9 A. Please define what you mean by 10 "economic theory." 11 Q. Well, sure. I mean, would you 12 agree that the field of economics, like 13 there's, for example -- let me strike that. 14 There's an economics department 15 at Dartmouth, for example, correct? 16 A. Yes. 17 Q. Okay. And you said you've 18 never taught an economics class there? 19 A. Correct. 20 Q. Okay. Or anywhere, correct? 21 A. Correct. 22 Q. Okay. For any of the course 23 subject matter that would be subject to a 24 Ph.D in economics, you wouldn't characterize</p>	<p style="text-align: right;">Page 28</p> <p>1 Q. Sure. I don't disagree with 2 you that there's some level of crossover, but 3 do you agree that economics is a separate and 4 distinct discipline from marketing? 5 A. I do not. Marketing is really 6 a combination of multiple disciplines, which 7 is why the premier journal, the Journal of 8 Consumer Research, has in their description 9 of why the journal was formed was to 10 encourage researchers from multiple 11 disciplines, including economics, to study 12 the intersection between consumer research 13 and economics, because we're talking about 14 economics, it's true also for psychology, 15 anthropology, etcetera. 16 So it is very difficult for me 17 to say that as a consumer researcher that I 18 don't have any knowledge of economics. 19 Q. I'm not saying that you don't 20 have any knowledge of economics. I'm just 21 asking if you would agree that it's a 22 separate discipline. 23 A. Is there a separate degree in 24 economics, yes.</p>
<p style="text-align: right;">Page 27</p> <p>1 yourself as an expert on any of that, would 2 you? 3 A. I'm sorry, what do you mean by 4 "any of that"? 5 Q. Well, any -- let me reframe. 6 So you had to do quite a bit of 7 work to get your Ph.D in marketing, correct? 8 A. Yes. 9 Q. Okay. Would you imagine that 10 there's -- to get a Ph.D in economics, you 11 have to also do quite a bit of work that's 12 different? 13 A. Yes. And I'm sure there's some 14 overlap as well. 15 For example, in a Ph.D program, 16 and I was in a Ph.D program in the business 17 school where people were getting their Ph.Ds 18 with different specializations, and we all 19 had to take core classes, so our core classes 20 overlapped. And then we had what you might 21 call elective, so they're not called that in 22 a Ph.D program. So we all had core classes, 23 and then elective classes for our 24 specialization. Yeah.</p>	<p style="text-align: right;">Page 29</p> <p>1 Q. Okay. And, for example, at 2 Dartmouth there's a separate department of 3 economics that has a separate faculty of 4 professors and Ph.Ds who teach economics, 5 correct? 6 A. Yes. And since the time that 7 I've been at the Tuck School of Business at 8 Dartmouth, three of the faculty members from 9 the department of economics at Dartmouth 10 College in the college of arts and sciences 11 are now faculty members in the Tuck School of 12 Business. 13 Q. Okay. Faculty members of what 14 exactly? 15 A. We are all faculty members of 16 management with subspecialties. 17 Q. Okay. And their subspecialty, 18 for example, would be the economics side of 19 what you would study to get an MBA from Tuck, 20 correct? 21 A. Yes. 22 Q. Okay. Do you have any what I 23 would call -- well, are you familiar with the 24 prescription drug approval process in the</p>

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<p>1 United States?</p> <p>2 A. I am not an expert, and don't</p> <p>3 have an opinion on that.</p> <p>4 Q. Okay. You do some</p> <p>5 health-related messaging initiatives, though,</p> <p>6 don't you? And you study -- I believe you</p> <p>7 said one of your consumer behavior sort of</p> <p>8 sub-research interest was health choices,</p> <p>9 correct?</p> <p>10 A. Yes.</p> <p>11 Q. Okay. So does that -- do you</p> <p>12 have some level of knowledge of how</p> <p>13 prescription drugs are approved in the US?</p> <p>14 A. I am an expert on how consumers</p> <p>15 make health-related decisions. I am not an</p> <p>16 expert on the approval process for health</p> <p>17 products and services.</p> <p>18 Q. Okay. Do you know what an NDA</p> <p>19 is, for example?</p> <p>20 A. No.</p> <p>21 Q. What about an ANDA?</p> <p>22 A. No.</p> <p>23 Q. Okay. Do you at least have an</p> <p>24 understanding that prescription drugs can't</p>	<p>1 MR. HONIK: You can stay on.</p> <p>2 It will just take a second, right?</p> <p>3 Thank you.</p> <p>4 Sorry for the interruption.</p> <p>5 (Pause.)</p> <p>6 BY MR. DAVIS:</p> <p>7 Q. Okay. So just to clarify my</p> <p>8 last question, you do understand that</p> <p>9 prescription drugs have to be pre-approved in</p> <p>10 the US, but I think your testimony is that</p> <p>11 you don't know much beyond just that fact, is</p> <p>12 that right?</p> <p>13 MR. GOLDBERG: Objection to</p> <p>14 form.</p> <p>15 A. That is not what I said. You</p> <p>16 asked me the question, and I answered it.</p> <p>17 And you did not ask me about anything beyond</p> <p>18 that, because that is vague, I don't know</p> <p>19 what beyond that means.</p> <p>20 BY MR. DAVIS:</p> <p>21 Q. Okay. So, well, let me</p> <p>22 rephrase it.</p> <p>23 What you're saying is you're</p> <p>24 generally familiar with the fact that</p>
Page 31	Page 33
<p>1 just simply be sold in the United States,</p> <p>2 that they actually have to go through a</p> <p>3 pre-approval process?</p> <p>4 A. Yes.</p> <p>5 Q. You shrugged a little bit</p> <p>6 there. Is there some level of confusion</p> <p>7 or...</p> <p>8 A. I shrugged because there were</p> <p>9 two questions, but I decided to answer</p> <p>10 because it was approval and pre-approval.</p> <p>11 And that's okay.</p> <p>12 Q. Sure. And if any of my</p> <p>13 questions are unclear, just ask me for</p> <p>14 clarification.</p> <p>15 A. Thank you.</p> <p>16 MR. HONIK: Before you proceed.</p> <p>17 Maureen, I have an e-mail from someone</p> <p>18 saying they're waiting to get in. I</p> <p>19 don't know who is letting people into</p> <p>20 the Zoom.</p> <p>21 THE WITNESS: Clearly I'm not.</p> <p>22 THE VIDEOGRAPHER: Do you want</p> <p>23 to go off the record so I can let them</p> <p>24 in?</p>	<p>1 prescription drugs have to be pre-approved in</p> <p>2 the US, but you are not familiar with the</p> <p>3 details of how that happens?</p> <p>4 A. I am not an expert on the</p> <p>5 pre-approval or the approval process --</p> <p>6 Q. Okay.</p> <p>7 A. -- for prescription drugs.</p> <p>8 Q. And likewise, is it your</p> <p>9 testimony that you would not have any</p> <p>10 expertise in FDA regulations regarding</p> <p>11 prescription pharmaceuticals after the point</p> <p>12 of approval?</p> <p>13 A. Could you repeat that?</p> <p>14 Q. Sure.</p> <p>15 Would it likewise be your</p> <p>16 testimony that you don't have any particular</p> <p>17 expertise regarding FDA regulations of</p> <p>18 prescription pharmaceuticals after the point</p> <p>19 of approval?</p> <p>20 A. I don't understand the</p> <p>21 question.</p> <p>22 Q. Sure.</p> <p>23 Do you understand that there</p> <p>24 are FDA regulations of approved prescription</p>

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<p>1 pharmaceuticals?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. Have you studied them in</p> <p>4 any detail?</p> <p>5 A. You would have to be more</p> <p>6 specific.</p> <p>7 Q. Have you studied those FDA</p> <p>8 regulations that you just testified existed</p> <p>9 in any detail?</p> <p>10 A. What does it mean "in any</p> <p>11 detail"?</p> <p>12 Q. Have you looked at the -- for</p> <p>13 example, have you looked at Title 21 of the</p> <p>14 Code of Federal Regulations?</p> <p>15 A. No.</p> <p>16 Q. Okay. Have you looked at any</p> <p>17 FDA regulations regarding prescription</p> <p>18 pharmaceuticals?</p> <p>19 A. You would need to be more</p> <p>20 specific.</p> <p>21 Q. Sure.</p> <p>22 You testified you were retained</p> <p>23 in this case in, I think, November or</p> <p>24 December of last year you said, correct?</p>	<p>1 at what the FDA regulations are regarding</p> <p>2 cGMPs?</p> <p>3 A. I am not an expert on</p> <p>4 manufacturing processes. I'm an expert on</p> <p>5 consumer decision-making.</p> <p>6 Q. Okay. Have you reviewed any</p> <p>7 FDA or congressional definitions of</p> <p>8 adulteration and misbranding of drugs?</p> <p>9 A. First, those were multiple</p> <p>10 questions. Could you ask, and be specific.</p> <p>11 Q. Sure, I'll break it down.</p> <p>12 Have you reviewed any FDA or</p> <p>13 congressional definitions of "adulteration"?</p> <p>14 A. No.</p> <p>15 Q. Okay. Same question for</p> <p>16 "misbranding."</p> <p>17 A. No.</p> <p>18 Q. You don't have any expertise in</p> <p>19 chemistry, do you?</p> <p>20 A. Please define "expertise in</p> <p>21 chemistry."</p> <p>22 Q. Have you studied chemistry</p> <p>23 ever?</p> <p>24 A. Only in school, high school.</p>
Page 35	Page 37
<p>1 A. Yes.</p> <p>2 Q. Since that time, do you recall</p> <p>3 looking at, as part of your work on this</p> <p>4 case, any FDA regulations regarding</p> <p>5 prescription pharmaceuticals?</p> <p>6 A. As is outlined in my report, I</p> <p>7 looked at some FDA-sourced material related</p> <p>8 to the valsartan recall.</p> <p>9 Q. That would be FDA announcements</p> <p>10 and the like specifically related to</p> <p>11 valsartan, correct?</p> <p>12 A. To the best of my recall, yes.</p> <p>13 Q. Okay. Do you recall looking at</p> <p>14 any FDA regulations of general applicability</p> <p>15 to prescription pharmaceuticals as part of</p> <p>16 your work in this case?</p> <p>17 A. Not that I recall.</p> <p>18 Q. Do you know what cGMPs are?</p> <p>19 A. I know what the acronym stands</p> <p>20 for.</p> <p>21 Q. Okay. What is that?</p> <p>22 A. Current manufacturing -- sorry,</p> <p>23 current good manufacturing practices.</p> <p>24 Q. Okay. Have you actually looked</p>	<p>1 Q. Okay. So you would not call</p> <p>2 yourself an expert chemist?</p> <p>3 A. No.</p> <p>4 Q. How about toxicology?</p> <p>5 A. I would not consider myself an</p> <p>6 expert in toxicology.</p> <p>7 Q. I'm going to mark your report,</p> <p>8 Dr. Keller, as Exhibit 2.</p> <p>9 (Whereupon, Keller Exhibit</p> <p>10 Number 2 was marked for</p> <p>11 identification.)</p> <p>12 MR. GOLDBERG: She has a copy</p> <p>13 of it.</p> <p>14 A. A copy of my report, yes. It's</p> <p>15 okay, I'm happy to use yours.</p> <p>16 BY MR. DAVIS:</p> <p>17 Q. You can keep mine, the marked</p> <p>18 copy, but if you feel more comfortable</p> <p>19 reviewing yours, that's fine.</p> <p>20 A. No, I'm fine with either copy.</p> <p>21 MR. DAVIS: Do you want a copy,</p> <p>22 Seth?</p> <p>23 MR. GOLDBERG: I'll take it</p> <p>24 just for recordkeeping purposes.</p>

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1 Thank you.
2 BY MR. DAVIS:
3 Q. Do you recognize what I've
4 handed to you as your expert report in this
5 case?
6 A. Yes.
7 Q. Okay. In drafting that expert
8 report, did you familiarize yourself at all
9 with Federal Rule of Civil Procedure 26 which
10 governs the use of an expert report in
11 federal court litigation?
12 A. No, I did not do it for this
13 case, but I did in the past when I had to
14 create an expert witness report.
15 Q. I'm going to read a statement
16 from that rule, and I'm going to ask you if
17 you feel your report complies with that. It
18 says, "The report must contain a complete
19 statement of all opinions the witness will
20 express, and the basis and reasons for them."
21 Do you feel that your report
22 complies with that provision of Rule 26?
23 A. Yes.
24 Q. Okay. Thank you.

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1 So there are no opinions that
2 you would be seeking to offer in this case
3 that are not in your report, is that correct?
4 A. Yes.
5 Q. And you've cited everything
6 that -- to the best of your ability, you've
7 cited everything that would support your
8 opinions in that report?
9 A. No, I cannot cite everything
10 that would support my opinions. This is a
11 subset of citations that would support my
12 opinions.
13 Q. Sure. Let me reframe the
14 question.
15 Are there any cites that are
16 out there that you intended to put in your
17 report that didn't make it in, to the best of
18 your memory and knowledge?
19 MR. GOLDBERG: Objection to
20 form.
21 A. Yeah, I don't know how to
22 answer the question.
23 BY MR. DAVIS:
24 Q. Well, I'm just asking, and

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1 maybe I should rephrase it, is, are there any
2 citations out there to anything that you
3 neglected to put in your report that you want
4 to tell me about today?
5 A. Well, I did not cite many of my
6 own publications because I felt that my
7 experience and my opinions reflected that
8 research expertise.
9 Q. Okay. So with the exception of
10 your research in publications, is there any
11 citation that's not in your report that you'd
12 like to tell me about today?
13 A. No.
14 Q. Okay. I believe your report is
15 signed January 12, 2022, is that right? I
16 believe that would be on the last page of
17 your report.
18 A. Yes.
19 Q. Do you recognize that as your
20 signature?
21 A. This one isn't signed.
22 MR. DAVIS: Seth, do you know
23 why that would be?
24 MR. GOLDBERG: I don't. I

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1 don't know how you would have a not
2 signed copy. That's interesting.
3 Can I see what you have there?
4 THE WITNESS: (Handing).
5 MR. DAVIS: It looks like it's
6 a digital signature. Perhaps it just
7 got -- when it got printed, that got
8 removed from the printing.
9 A. My copy is signed.
10 BY MR. DAVIS:
11 Q. My electronic copy is also
12 signed, so it must be a printing error.
13 Okay. So looking at --
14 A. Can I have --
15 MR. HONIK: Here's one with a
16 signature if you want it.
17 MR. DAVIS: Should we trade
18 out?
19 MR. GOLDBERG: Sure. We can do
20 that later.
21 BY MR. DAVIS:
22 Q. So when you signed your report
23 on January 12, 2022, did you feel that you
24 had set forth your complete statement of your

<p>Page 42</p> <p>1 opinions and the basis and reasons for them?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. You didn't do any kind</p> <p>4 of survey or empirical study as part of your</p> <p>5 assignment in this case, did you?</p> <p>6 A. No, because I felt that there</p> <p>7 was evidence from consumers as well as</p> <p>8 literature from consumers that were</p> <p>9 sufficient to support my opinions.</p> <p>10 Q. We'll get into that a little</p> <p>11 bit later.</p> <p>12 But your answer is no, you did</p> <p>13 not do a survey or any kind of empirical</p> <p>14 study as part of your assignment in this</p> <p>15 case?</p> <p>16 A. Yes.</p> <p>17 Q. Okay. Have you been asked to</p> <p>18 at some point in the future?</p> <p>19 A. No.</p> <p>20 Q. I think you said earlier that</p> <p>21 you've done some consumer messaging in the</p> <p>22 field of healthcare, is that correct?</p> <p>23 A. Yes.</p> <p>24 Q. Okay. Can you describe that</p> <p>Page 43</p>	<p>Page 44</p> <p>1 or service valuation. And the messages</p> <p>2 contain information on the benefits and the</p> <p>3 costs of the advocated action to help</p> <p>4 consumers make the value determination.</p> <p>5 Q. Well, let's move away from the</p> <p>6 theoretical for a moment.</p> <p>7 And on the specific sort of</p> <p>8 messaging that you've designed for healthcare</p> <p>9 consumers, can you give me some examples of</p> <p>10 what the substance of those messages conveyed</p> <p>11 to them were?</p> <p>12 A. So first I object to it being</p> <p>13 characterized as "theoretical," because it is</p> <p>14 also very practical.</p> <p>15 And an example of the message</p> <p>16 would be, you know, here are the benefits of</p> <p>17 following -- in the message, there's a</p> <p>18 portion of the message that would focus on,</p> <p>19 Here are the benefits of following the</p> <p>20 advocated recommendations.</p> <p>21 Q. Let me --</p> <p>22 A. For example --</p> <p>23 Q. I didn't mean to cut you off.</p> <p>24 A. For example, one of my studies</p> <p>Page 45</p>
<p>1 work generally to me?</p> <p>2 A. I use my expertise in consumer</p> <p>3 decision-making to design communications that</p> <p>4 would create value for consumers.</p> <p>5 Q. And I think -- so is it fair to</p> <p>6 say that that messaging is directed to</p> <p>7 consumers specifically?</p> <p>8 A. In large part. I have also</p> <p>9 done work to design health communication to</p> <p>10 physicians to help them create value for</p> <p>11 consumers.</p> <p>12 Q. What was -- let's start with</p> <p>13 the messaging to consumers that you</p> <p>14 described. What would be the substance of</p> <p>15 those messaging campaigns that you've</p> <p>16 designed?</p> <p>17 A. As I've stated in my report,</p> <p>18 message factors are part of one of my</p> <p>19 frameworks, acronym MICI -- that stands for</p> <p>20 message-individual-contextual factors and the</p> <p>21 interaction between those -- are very</p> <p>22 important, so the message part of that is</p> <p>23 very important for consumers to consider as</p> <p>24 inputs when they are making a health product</p>	<p>1 is on encouraging women to get a -- to get</p> <p>2 screened regularly for mammograms, and so,</p> <p>3 you know, I would list the benefits of</p> <p>4 getting a mammogram, and then also try to</p> <p>5 anticipate some of the costs from a consumer</p> <p>6 point of view and try to overcome those.</p> <p>7 So, for example, a potential</p> <p>8 cost for a consumer might be the discomfort</p> <p>9 or pain from the mammogram testing procedure,</p> <p>10 and in my message I might include some coping</p> <p>11 methods for that, including managing</p> <p>12 expectations and maybe, you know, asking them</p> <p>13 to check to see if they can take pain</p> <p>14 medication and the like.</p> <p>15 Q. Okay. So you've given me an</p> <p>16 example, I believe, of an advocated</p> <p>17 recommendation, I believe that's the term you</p> <p>18 used, and that's getting screened for a</p> <p>19 mammogram. That would be an example of an</p> <p>20 advocated recommendation --</p> <p>21 A. Yes.</p> <p>22 Q. -- is that correct?</p> <p>23 For mammograms, let's run with</p> <p>24 that example. For a mammogram, are there any</p>

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1 sort of guidances or anything similar to that
 2 about when and how often individuals should
 3 get screened?
 4 A. Yes.
 5 Q. Okay. Would some of the
 6 content that's conveyed with that advocated
 7 recommendation, for example, cite to those
 8 guidances around compliance and the like?
 9 A. In the mammogram example,
 10 because there are multiple guidelines -- and
 11 this again supports my MICI framework because
 12 based on some individual differences such as
 13 your age, your health status, for example, or
 14 history of breast cancer, or cancer as
 15 another example, contexts in which the
 16 decision is made, you know, whether it is --
 17 whether one has a relationship with a primary
 18 care physician or specialist, all of those
 19 factors are considered in the design of -- in
 20 my research, in the design of multiple
 21 communication that is tailored to different
 22 audiences.
 23 Q. So I believe you said that
 24 there was -- there were some guidances, for

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1 example, about when and how often to get
 2 screened for a mammogram, correct?
 3 A. Yes.
 4 Q. Okay. Who issues those
 5 guidances?
 6 A. I don't know. I work with
 7 physicians, or someone from the medical
 8 community, that gives me the information, and
 9 I use that information in the messages.
 10 When I have to do an experiment
 11 where it's a hypothetical situation, I
 12 don't -- you know, I go through a human
 13 subject review committee.
 14 When it's in a practical
 15 context, there are other reviewers.
 16 Q. So I believe you said you did
 17 use that information regarding when and how
 18 often to get screened in the messages you
 19 designed, for example, in this instance for
 20 mammograms, correct?
 21 A. Yes.
 22 Q. Okay. Have you done any
 23 similar messaging for pharmaceutical
 24 products?

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1 A. Yes.
 2 Q. Does the messages supporting
 3 the advocated recommendation for
 4 pharmaceuticals often center around
 5 compliance?
 6 A. Sorry, I don't understand the
 7 question.
 8 Q. Sure.
 9 For pharmaceuticals that you've
 10 given advocated recommendations for, has the
 11 messaging accompanying the advocated
 12 recommendation often incorporated messaging
 13 around patient compliance, i.e., you know,
 14 staying on schedule with the drug and
 15 following -- you know, taking it as
 16 prescribed, etcetera?
 17 A. The study that's coming to my
 18 mind now as I answer your question, so the
 19 answer is yes, and I'm going to qualify it.
 20 It's for a diabetes medication,
 21 and my messaging is text messaging, and there
 22 are over 60 different types of text messages
 23 to remind -- in different formats to remind
 24 people to not only stay on schedule for their

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1 medication, but also diet and exercise and
 2 screening.
 3 Q. Okay. Thank you for that.
 4 I see that you've also designed
 5 some messaging around COVID vaccine
 6 hesitancy, correct?
 7 A. I'm sorry, what are you
 8 referring to so I can make sure I understand
 9 the context?
 10 Q. Are you on some kind of panel
 11 related to designing messaging to tackle
 12 COVID vaccine hesitancy?
 13 A. I am -- I would not
 14 characterize it as a panel. I would say that
 15 I am a member of a team that -- of multiple
 16 teams. One of the teams, yes.
 17 Q. Sorry.
 18 A. I apologize, I started to
 19 explain. You didn't ask that. You just
 20 asked am I a member of panel, and it's not a
 21 panel, it was a team, and I started
 22 describing it, but you may not need that.
 23 Q. Sure. I mean, that was going
 24 to be my next question, is, describe to me

<p style="text-align: right;">Page 50</p> <p>1 what it is and what your involvement with it 2 is. 3 A. So I'm on multiple ones. 4 Starting with the research that I'm doing is 5 to, and this is gathering primary data, is to 6 encourage those with COVID-19 vaccine 7 hesitancies to either get vaccinated or to 8 get boosted. It's actually in Massachusetts. 9 Q. Okay. 10 A. The second study I'm thinking 11 about is on a team to understand how 12 behavioral economics -- how behavioral 13 economic principles have worked during the 14 pandemic to reduce vaccine hesitancy and to 15 encourage vaccination and COVID-19 booster 16 shots. 17 And the third one is on a large 18 team organized by the Get the Medication 19 Right X, GTMRx, and that study, or that 20 publication/paper, it is not a peer-reviewed 21 paper, but that paper that is put out by that 22 institution, I was part of a team to think 23 about structural issues, process issues, 24 system issues related to -- and this is why I</p>	<p style="text-align: right;">Page 52</p> <p>1 to encourage people to get vaccinated; should 2 we frame the message positively or 3 negatively; should we say here's what you 4 gain if you get the vaccine, here's what you 5 lose if you don't get the vaccine. So those 6 are just examples, okay, just to give you a 7 few. 8 And so, you know, how well 9 have -- and there's a variety of principles, 10 how well have those -- sometimes they call 11 them nudges, a lot of the times behavioral 12 economists call them nudges, the 13 interventions that they use to nudge 14 consumers to take the recommended or 15 advocated actions. But those are examples. 16 And in the first study that I 17 was describing where I'm actually doing the 18 study here in the State of Massachusetts, we 19 are looking at -- and I'm with a team that is 20 funded -- that sits in the Mass 21 General/Brigham Young Hospital and the 22 Harvard Medical School, and it's a center 23 for -- that's related to use of behavioral 24 economics to improve medication adherence.</p>
<p style="text-align: right;">Page 51</p> <p>1 was invited as an expert -- related to MICI, 2 the messaging, individual differences, and 3 the context, and how we might improve those 4 to not only address the current pandemic, but 5 any future pandemics. 6 Q. Let's take the second one for a 7 moment, and this might be a fruitful example 8 to help me understand what you mean by 9 "behavioral economics." 10 So I guess draw the connection 11 for me between overcoming COVID vaccine 12 hesitancy and how behavioral economics shaped 13 into that. 14 A. Right. And I can do that, and 15 actually will also give you insight on the 16 first study, which is based on behavioral 17 economic principles as well. 18 So one example -- and there are 19 many, many behavioral economists out there 20 and, as I said, made up of people with 21 multiple disciplinary backgrounds, and they 22 have tried different things such as, should 23 we pay people to get vaccinated is one 24 example; should we create a lottery, right,</p>	<p style="text-align: right;">Page 53</p> <p>1 Q. Okay. 2 A. And -- okay. And this 3 particular -- I'm doing the study with that 4 group, with a subset of that group, and we 5 are looking at some eligible patients or 6 consumers get -- why one should get the 7 vaccine. Some get a message on how to get 8 the vaccine, and that includes the booster. 9 And the third arm is usual care. 10 And then we track and see which 11 message is the most effective compared to 12 each other, one arm to the other, in a 13 randomized control trial. 14 Q. Okay. Let me try and see if I 15 understand this. 16 So I think you mentioned that 17 some of these nudges, for example, for 18 behavioral economics might have been a 19 lottery or to pay people to get vaccinated or 20 what they might gain or lose, for example, 21 losing a job, or something like that? 22 A. No, gain or loss, sorry, I 23 refer to in a framed message. 24 Q. Okay. Understood.</p>

<p style="text-align: right;">Page 54</p> <p>1 So it seems like the baseline 2 for all of that is that it's like a monetary 3 incentive, is that -- 4 A. That is incorrect. Monetary 5 incentives are a subset of the -- as nudges 6 used in behavioral economics. For example, I 7 mentioned frames, you know, you're focused on 8 the benefits or the gains versus the losses 9 are a very popular behavioral economics 10 messaging, not related to money, messaging 11 nudge, and, in fact, the foundation for that 12 is prospect theory, and to prominent 13 economists Kahneman and Tversky, both Nobel 14 Prize laureates, who created the foundation 15 for these and other nudges. 16 Q. So -- and perhaps monetary 17 incentives could be a subset, I suppose, is 18 what you're saying? 19 A. Yes. 20 Q. Okay. Gotcha. 21 So it's any kind of reward or 22 disincentive, sort of, that affects behavior, 23 I suppose. Is that a more accurate, 24 wholistic way of capturing the idea?</p>	<p style="text-align: right;">Page 56</p> <p>1 you're saying there that the -- in ranking -- 2 there's empirical evidence out there that in 3 ranking topics of importance for medical 4 therapy, that consumers and physicians place 5 safety and efficacy routinely at the top of 6 those priorities? 7 A. So because you are referencing 8 a specific paper, I will say that in this 9 particular paper they look at -- so, for 10 example, there are about 108 consumers, and 11 about 115 or so, a little higher, physicians, 12 that 33 consumers rated safety as the most 13 important topic, the topic of importance for 14 them during initiation of medical therapy. 15 So it's very important to get the details. 16 And what that means is 17 basically 70-plus consumers did not rate 18 safety as the most important topic during the 19 initiation of medical therapy. 20 So I just want to make sure 21 that this data is understood correctly, that 22 it will be a range of -- even in the study, a 23 range of consumer responses as to the 24 importance of specific features and the</p>
<p style="text-align: right;">Page 55</p> <p>1 A. I would prefer to rephrase that 2 in terms of benefits and costs. If you think 3 about rewards as benefits, there's some 4 overlap, but not perfect overlap. 5 And by costs, I am not just 6 referring to monetary costs. There are 7 switching costs, transaction costs, 8 convenience costs. So just want to clarify 9 that we are talking about value as a function 10 of costs and benefits, and those benefits 11 could be a range of benefits. 12 Q. So, and I'm happy to adopt your 13 terminology there. 14 It's essentially cost benefit 15 for behavioral economics; what are the 16 benefits of the behavior, what are the costs 17 of the behavior, is that right? 18 A. (Nodding in the affirmative). 19 Q. Okay. Flip, if you don't mind, 20 in your report, which is Exhibit 2, to 21 page 17, and that's footnote 36 specifically. 22 That footnote reads -- let me 23 paraphrase it, I guess. I don't want to read 24 the whole thing. But essentially is what</p>	<p style="text-align: right;">Page 57</p> <p>1 weight -- sorry, their -- yeah, weight on 2 those features, and that, as I say in my 3 report, is likely to change during the 4 consumers' and the physicians' experience 5 with the consumer taking the drug over time. 6 Q. Okay. But to -- but what 7 you're saying is the results of that survey 8 show that numerically the most common answer 9 was safety number one, efficacy number two? 10 A. During the -- topic of 11 importance during the initiation of medical 12 therapy. 13 Q. Okay. And did you look at the 14 survey design and read the article in citing 15 it in this paper? 16 A. Yes. 17 Q. Okay. All right. Thank you. 18 Do you feel like it was a 19 well-designed survey? 20 MR. GOLDBERG: Objection to 21 form. 22 A. I -- it was well designed. It 23 was a good survey. Are there things that 24 could have been -- could have been done</p>

<p style="text-align: right;">Page 58</p> <p>1 differently? Yes.</p> <p>2 BY MR. DAVIS:</p> <p>3 Q. Okay. Well, would you agree it</p> <p>4 was reliable enough for you to cite it in</p> <p>5 your report?</p> <p>6 A. Yes. I mean, you know, it's --</p> <p>7 yes.</p> <p>8 Q. You wouldn't cite any kind of</p> <p>9 study or survey or piece of literature in</p> <p>10 your report that you thought had significant</p> <p>11 reliability issues, would you?</p> <p>12 A. No. The quality of the report</p> <p>13 is the most important.</p> <p>14 Q. So back to your messaging</p> <p>15 campaigns that you've done, and maybe let's</p> <p>16 stick with COVID as the example. In the</p> <p>17 COVID messaging -- vaccine messaging</p> <p>18 campaigns, how were concerns about safety and</p> <p>19 efficacy addressed in the communications that</p> <p>20 supported the advocated recommendation, which</p> <p>21 was to get vaxed or boosted?</p> <p>22 A. I mentioned multiple studies,</p> <p>23 but I will talk about the question -- I can</p> <p>24 answer the question for one of those, which</p>	<p style="text-align: right;">Page 60</p> <p>1 to be shown as effective for mitigating the</p> <p>2 risk associated with the COVID-19 virus.</p> <p>3 Q. Is part of the messaging that</p> <p>4 the vaccines have gone through an approval</p> <p>5 process that demonstrated, for example, their</p> <p>6 efficacy and safety?</p> <p>7 A. I'm sorry, can you repeat that?</p> <p>8 Q. Was one of the messages that</p> <p>9 you designed, was the content of one of those</p> <p>10 messages, did that emphasize the fact that</p> <p>11 the vaccines had gone through an approval</p> <p>12 process to demonstrate scientifically their</p> <p>13 safety and efficacy?</p> <p>14 A. I don't recall.</p> <p>15 Q. Okay. You sit on the COVID</p> <p>16 vaccine hesitancy task force, right?</p> <p>17 A. One of them, yes.</p> <p>18 Q. Let me just mark something as</p> <p>19 an exhibit then.</p> <p>20 MR. DAVIS: This is being</p> <p>21 handed to the reporter to be marked as</p> <p>22 Keller 3.</p> <p>23 (Whereupon, Keller Exhibit</p> <p>24 Number 3 was marked for</p>
<p style="text-align: right;">Page 59</p> <p>1 is the three arms of how and why and usual</p> <p>2 care messaging.</p> <p>3 So the messaging goes to people</p> <p>4 who are eligible for the vaccine or the</p> <p>5 booster, and I rely on the hospital system</p> <p>6 and the electronic database, health record</p> <p>7 database. I am not involved with actually</p> <p>8 sending out these messages, I only design the</p> <p>9 messages, but they -- the rest of the team</p> <p>10 works on the eligibility of the participants.</p> <p>11 Q. Okay. So, and you said you</p> <p>12 were responsible for designing the content of</p> <p>13 the message, correct?</p> <p>14 A. The letter that goes to the</p> <p>15 patients, yeah.</p> <p>16 Q. So what sort of -- in terms of</p> <p>17 the content of the messages that you</p> <p>18 designed, what sort of content did you</p> <p>19 include to address safety or efficacy</p> <p>20 concerns that may exist amongst the un- or</p> <p>21 undervaccinated?</p> <p>22 A. In these particular messages,</p> <p>23 to the best of my recall, we use language</p> <p>24 that the vaccine is -- has been demonstrated</p>	<p style="text-align: right;">Page 61</p> <p>1 identification.)</p> <p>2 MS. ANDRAS: Since we don't</p> <p>3 have electronic exhibits, could you</p> <p>4 for the record and counsel who don't</p> <p>5 have copies, introduce the exhibit</p> <p>6 with a little more specificity?</p> <p>7 MR. DAVIS: Sure. And I'll do</p> <p>8 that on the record when I'm going</p> <p>9 through it with the witness.</p> <p>10 BY MR. DAVIS:</p> <p>11 Q. For the record, this Exhibit 3</p> <p>12 is a -- the cover page to it is a report to</p> <p>13 the GTR -- GTMRx National Task Force, and</p> <p>14 it's titled "Background and Resources to</p> <p>15 Build Vaccine Confidence in the Health</p> <p>16 Neighborhood" dated March 2021.</p> <p>17 Do you see that, Dr. Keller?</p> <p>18 A. Yes.</p> <p>19 Q. And if you flip to the -- if</p> <p>20 you go one, two, three, four pages in, do you</p> <p>21 see your name under "Task Force Participants"</p> <p>22 there?</p> <p>23 A. Yes.</p> <p>24 MR. GOLDBERG: John, let me</p>

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1 just say, if you're going to ask about
2 the document, I do think the witness
3 should be able to take a chance to
4 review it.
5 MR. DAVIS: I mean, I have very
6 limited questions regarding it.
7 BY MR. DAVIS:
8 Q. Why don't I ask them, and if
9 you feel like you want to review it, then we
10 can go off the record and you can take a look
11 at it.
12 A. Can I just stop you for a
13 moment?
14 Q. Sure.
15 A. I'm going to ask you to review
16 it regardless of the question you ask, so I
17 don't want you to think that --
18 Q. Sure.
19 MR. DAVIS: Why don't we go off
20 the record, then, and you can review
21 it.
22 MR. GOLDBERG: I think we're
23 going to stay on the record. You can
24 review it. If it takes more than a

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1 few minutes, then we can go off the
2 record. That's the rule in this case.
3 The rule is that we start
4 reviewing, if it's going to take a
5 long time, then we'll go off the
6 record. But that's what we do in this
7 case.
8 (Witness reviewing document.)
9 A. Okay.
10 BY MR. DAVIS:
11 Q. And I promise I don't have
12 detailed questions for you on this.
13 A. Thank you. I --
14 MR. GOLDBERG: There's not a
15 question pending. Just let counsel
16 ask a question.
17 BY MR. DAVIS:
18 Q. So you saw on the first page
19 that this is dated March 2021, correct?
20 A. Yes.
21 Q. At the time of March 2021,
22 COVID vaccines were operating under an
23 emergency use authorization, correct, or a
24 EUA?

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1 A. I'm not sure.
2 Q. Why don't you flip to page,
3 what's numbered as page 6 in the bottom left
4 corner. You'll see some numbering in the
5 bottom left corner, there's a page 6.
6 Do you see there's a third
7 block bullet, a blue block? Do you see that?
8 Actually yours is black and white. Sorry.
9 There's a third block there
10 that says, "COVID-19 vaccines have been
11 approved under emergency use authorization."
12 Do you see that?
13 A. Yes.
14 Q. Okay. These vaccines now have
15 full approval, correct, full FDA approval?
16 Is that your understanding?
17 A. I'm not sure.
18 Q. Okay. Do you see that there's
19 a third bullet under that bullet I pointed
20 out to you, a smaller bullet that says,
21 "Others warn that EUAs exacerbate the
22 deterioration of the public's confidence in
23 science"?
24 Do you see that?

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1 A. I need a moment to just look at
2 the context.
3 (Witness reviewing document.)
4 A. Okay.
5 Q. Was that one of the findings of
6 this task force that's in this report that
7 you sat on, was that among the vaccine
8 hesitant there was -- some of that was
9 related to the fact at the time of this
10 report that the vaccines had not undergone a
11 full approval process?
12 MR. GOLDBERG: Objection to
13 form. Vague, mischaracterizes the
14 document.
15 A. Could you please be more
16 specific?
17 BY MR. DAVIS:
18 Q. Did you assist in drafting this
19 report?
20 A. I was a member of the task
21 force that reviewed certain sections of the
22 document, and participated in discussions on
23 the creation of the document.
24 Q. Let me just tell you where I'm

<p style="text-align: right;">Page 66</p> <p>1 going with this, which is that, would you 2 agree -- and maybe we can bypass all of this. 3 Would you agree that consumers and physicians 4 look at approval by the regulator as an 5 important piece of information to consider in 6 making a consumer choice? 7 A. You need to be more specific. 8 Those are two questions. 9 Q. What are the two questions in 10 there? 11 A. You said "consumers and 12 physicians." 13 Q. Okay. Well, let's take it from 14 the consumers first. So the same question, 15 just for consumers. 16 A. Could you repeat the question? 17 Q. Sure. 18 Would you agree that consumers 19 in making choices regarding medications or 20 medical therapy view approval by the 21 regulator as an important piece of 22 information? 23 A. There is a range of consumer 24 responses, as I have explained in my report,</p>	<p style="text-align: right;">Page 68</p> <p>1 other words, approved as safe and effective 2 by the FDA? Is that part of the messaging? 3 A. I do not recall. My task in 4 this project is to focus on the how versus 5 why components of that message. There are 6 other team members that are focused on other 7 aspects of who gets the message and the 8 context in which they get the message. 9 Q. Okay. Let's transition. 10 MR. GOLDBERG: John, if we are 11 transitioning, can we take a break? 12 MR. DAVIS: Sure. Yeah, that's 13 fine. 14 THE VIDEOGRAPHER: Off the 15 record at 10:43. 16 (Whereupon, a recess was 17 taken.) 18 THE VIDEOGRAPHER: Back on the 19 record at 11:04. 20 BY MR. DAVIS: 21 Q. Do you have any understanding 22 of how generic drugs specifically get 23 approved in the US? 24 A. No.</p>
<p style="text-align: right;">Page 67</p> <p>1 in various section -- subsections of Section 2 IV in my report, such as IV.B, that using 3 different decision rules, compensatory and 4 non-compensatory, some may and some may not. 5 Same with the MICI factors in 6 Section IV.C of my report, some consumers may 7 pay attention to the information or approval 8 from the FDA as part of the messaging that 9 they consider, and some may not. 10 For example, they may pay much 11 more attention to their individual health 12 status or the context such as their 13 relationship with the physician, rely on the 14 physician to give them guidance. 15 Q. Let's take it back to the COVID 16 vaccines for a second. 17 You're currently, I think you 18 testified, doing some messaging encouraging 19 vaccination and boosting, correct? 20 A. Yes. 21 Q. Okay. Is part of the substance 22 of that message that's being conveyed now 23 that these vaccines have full safety and 24 efficacy endorsement by the FDA; they're, in</p>	<p style="text-align: right;">Page 69</p> <p>1 Q. Do you have any understanding 2 of what -- how generic drugs are supposed to 3 compare to their brand counterparts? 4 MR. GOLDBERG: Objection to 5 form. Vague. 6 A. Please clarify. 7 BY MR. DAVIS: 8 Q. Sure. 9 What is a generic drug, can you 10 tell me that? 11 A. From a marketing perspective, a 12 generic drug is an unbranded drug. 13 Q. And compared to branded drugs, 14 what are unbranded drugs supposed to be in 15 comparison to them? 16 A. One thing they're supposed to 17 be is cheaper. 18 Q. Okay. Do you understand that 19 they're supposed to be therapeutically 20 equivalent? 21 A. In a prescription drug context, 22 yes. 23 Q. In fact, would you agree that 24 many aspects of our healthcare system rely on</p>

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1 an assumption that generic drugs are
2 therapeutically equivalent to their brand
3 counterparts?
4 A. Could you please repeat?
5 MR. DAVIS: Could you repeat
6 the question?
7 (Whereupon, the reporter read
8 back the question:
9 QUESTION: In fact, would you
10 agree that many aspects of our
11 healthcare system rely on an
12 assumption that generic drugs are
13 therapeutically equivalent to their
14 brand counterparts?)
15 MR. GOLDBERG: Objection.
16 Vague.
17 A. Many aspects of our healthcare
18 system, it's too -- it's not specific enough
19 for me.
20 BY MR. DAVIS:
21 Q. Okay. Are you familiar with
22 automatic generic substitution at the
23 pharmacy level as a concept?
24 A. Could you repeat that?

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1 Q. Are you familiar with automatic
2 generic substitution at the pharmacy level as
3 a concept?
4 A. What do you mean "as a
5 concept"?
6 Q. Well, let's take that off.
7 Are you familiar with automatic
8 generic substitution at the pharmacy level?
9 A. I know that -- I don't know who
10 does it, but I know that sometimes when
11 you -- as a consumer when you expect a
12 branded drug you are given a generic.
13 Q. Well, it's regardless of
14 whether a consumer expects a branded drug or
15 not, the substitution occurs, does it not?
16 MR. GOLDBERG: Objection to
17 form.
18 A. I don't know.
19 BY MR. DAVIS:
20 Q. Okay. Do you have any
21 familiarity with how reimbursement or
22 formulary decisions are made in response to
23 the market entry of a generic vis-à-vis the
24 brand?

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1 A. No, I am not an expert on that.
2 Q. Okay. Are you familiar with
3 the fact that when a physician writes a
4 prescription on a prescription pad, even if
5 the physician writes the brand name, that
6 oftentimes if there's a generic, the generic
7 will be dispensed because of generic
8 substitution laws?
9 A. I don't have an opinion on
10 that.
11 Q. And I believe you said you
12 don't know what generic manufacturers have to
13 demonstrate to the FDA to get their generic
14 drugs approved for sale in the US, correct?
15 A. I do not recall saying that.
16 Q. Okay. Well, then, let me ask
17 it then.
18 Are you aware --
19 A. Can you please repeat it?
20 Q. Are you aware of what generic
21 drug manufacturers have to demonstrate to the
22 FDA in order to get their generic drugs
23 approved for marketing and sale in the US?
24 A. I am not an expert. I don't

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1 have an opinion.
2 Q. Well, the question is do you
3 know.
4 A. No.
5 Q. Are you familiar with the fact
6 that generic pharmaceutical manufacturers do
7 not routinely engage in promotional
8 activities for their drugs?
9 A. I do not know.
10 Q. When I refer to FDA-approved
11 labeling, do you know what that means?
12 A. Could you be more specific?
13 Q. Sure.
14 Do you know what an
15 FDA-approved label is?
16 A. No.
17 Q. Have you looked at any
18 FDA-approved labeling for any of the generic
19 valsartan products at issue in this case?
20 A. I have looked at some labels of
21 valsartan. I do not know if they are
22 FDA-approved or not.
23 Q. In general terms, the labels
24 that you looked at, what kind of information

<p style="text-align: right;">Page 74</p> <p>1 did they contain?</p> <p>2 A. To the best of my recall, they</p> <p>3 contained the name of the drug, the dosage,</p> <p>4 the manufacturer, and the country of</p> <p>5 manufacture.</p> <p>6 Q. Did you see any section in</p> <p>7 those labels that had warnings or</p> <p>8 contraindications or side effect information,</p> <p>9 anything like that?</p> <p>10 A. I do not recall.</p> <p>11 Q. Okay. What about a listing of</p> <p>12 ingredients?</p> <p>13 A. I do not recall.</p> <p>14 Q. Would you agree that the</p> <p>15 purpose of those labels that you reviewed was</p> <p>16 to provide information regarding the drug?</p> <p>17 A. Please define "information."</p> <p>18 Q. Well, sure. I mean, you</p> <p>19 mentioned what it is, who manufactures it,</p> <p>20 things like that. Would that in your mind</p> <p>21 constitute information regarding the drug?</p> <p>22 A. In my mind it would constitute</p> <p>23 some information regarding the drug. There</p> <p>24 could be other information regarding the drug</p>	<p style="text-align: right;">Page 76</p> <p>1 A. No.</p> <p>2 Q. Have you ever studied health</p> <p>3 messaging to consumers or physicians</p> <p>4 regarding generic drugs vis-à-vis brand</p> <p>5 drugs?</p> <p>6 MR. GOLDBERG: Objection to</p> <p>7 form. Ambiguous.</p> <p>8 A. Could you repeat that, please?</p> <p>9 BY MR. DAVIS:</p> <p>10 Q. Sure.</p> <p>11 Have you ever studied any kind</p> <p>12 of health messaging to consumers or</p> <p>13 physicians regarding generic drugs?</p> <p>14 A. Not that I recall.</p> <p>15 Q. Okay. Not in your work in this</p> <p>16 case, and not ever, is that your testimony?</p> <p>17 A. I don't understand the</p> <p>18 question.</p> <p>19 Q. Sure. I'm trying to clarify</p> <p>20 whether your answer is you haven't looked at</p> <p>21 that in this case or you haven't looked at</p> <p>22 that at all ever.</p> <p>23 A. Okay. So can you repeat the</p> <p>24 question again so I understand the context?</p>
<p style="text-align: right;">Page 75</p> <p>1 that is not on the label or that I do not</p> <p>2 recall was on the label.</p> <p>3 Q. If the purpose of FDA-approved</p> <p>4 labeling was to provide information to</p> <p>5 consumers and physicians regarding the drug,</p> <p>6 what's in it, potential side effects,</p> <p>7 etcetera, would you disagree with that?</p> <p>8 A. Please repeat the question.</p> <p>9 Q. Would you disagree with the</p> <p>10 proposition that FDA-approved labeling is</p> <p>11 designed to provide to consumers and</p> <p>12 physicians certain information regarding the</p> <p>13 drug?</p> <p>14 MR. GOLDBERG: Objection to</p> <p>15 form. Foundation.</p> <p>16 A. I cannot answer that question.</p> <p>17 BY MR. DAVIS:</p> <p>18 Q. So you don't know the purpose</p> <p>19 of FDA-approved labeling?</p> <p>20 A. That was not the question you</p> <p>21 asked, but is that the question you're asking</p> <p>22 now?</p> <p>23 Q. Well, that's my new question,</p> <p>24 yes.</p>	<p style="text-align: right;">Page 77</p> <p>1 Q. Sure.</p> <p>2 The question that you said "no"</p> <p>3 to was whether you had had any occasion to</p> <p>4 look at health messaging to consumers or</p> <p>5 physicians regarding generic drugs, and I</p> <p>6 believe you said "no" to that, right?</p> <p>7 A. I'm going to qualify. If by</p> <p>8 "health messaging" you are also including</p> <p>9 what the FDA said about generic valsartan,</p> <p>10 then I did have a chance to look at that for</p> <p>11 this case.</p> <p>12 Q. I'm talking about from a</p> <p>13 general proposition, so regarding generic</p> <p>14 drugs generally, their uses, their benefits,</p> <p>15 what they are, etcetera.</p> <p>16 Have you ever looked at any</p> <p>17 generalized messaging to physicians or</p> <p>18 consumers regarding generic drugs as a</p> <p>19 therapeutic sort of class?</p> <p>20 A. Not that I recall.</p> <p>21 Q. Okay. Not in this case?</p> <p>22 A. I can't answer the question.</p> <p>23 Could you repeat the question?</p> <p>24 MR. DAVIS: Could you repeat</p>

<p style="text-align: right;">Page 78</p> <p>1 the question?</p> <p>2 (Whereupon, the reporter read</p> <p>3 back the following:</p> <p>4 QUESTION: I'm talking about</p> <p>5 from a general proposition, so</p> <p>6 regarding generic drugs generally,</p> <p>7 their uses, their benefits, what they</p> <p>8 are, etcetera.</p> <p>9 Have you ever looked at any</p> <p>10 generalized messaging to physicians or</p> <p>11 consumers regarding generic drugs as a</p> <p>12 therapeutic sort of class?</p> <p>13 THE WITNESS: Not that I</p> <p>14 recall.</p> <p>15 QUESTION: Okay. Not in this</p> <p>16 case?)</p> <p>17 A. So the challenge I'm facing is</p> <p>18 you asked about as a general proposition, and</p> <p>19 I answered, and then now you're saying "not</p> <p>20 in this case," and so I'm just trying to make</p> <p>21 sure I understand the question, which is a</p> <p>22 very specific proposition.</p> <p>23 BY MR. DAVIS:</p> <p>24 Q. Okay. So let me just try it</p>	<p style="text-align: right;">Page 80</p> <p>1 MR. DAVIS: Sure. For the</p> <p>2 record, this is an FDA resource from</p> <p>3 the FDA's website titled "Generic</p> <p>4 Drugs: Questions and Answers."</p> <p>5 BY MR. DAVIS:</p> <p>6 Q. Have you ever seen this</p> <p>7 document before, or this content on the FDA</p> <p>8 website?</p> <p>9 A. I would like to check my</p> <p>10 report. It looks familiar, but I'm not sure.</p> <p>11 Q. Sure. If you want to check</p> <p>12 your report, that's fine.</p> <p>13 (Witness reviewing document.)</p> <p>14 A. Okay. Thank you.</p> <p>15 Q. You don't see it in your</p> <p>16 report, do you?</p> <p>17 A. I do not.</p> <p>18 Q. Okay. And is it your testimony</p> <p>19 that you've never seen this before or</p> <p>20 reviewed it on the FDA's website?</p> <p>21 A. Correct, yes.</p> <p>22 Q. Okay. This, Dr. Keller, is an</p> <p>23 example of, like you asked for, of what I'm</p> <p>24 talking about here. Do you see that this is</p>
<p style="text-align: right;">Page 79</p> <p>1 again.</p> <p>2 In this case, have you looked</p> <p>3 at any generalized messaging to physicians or</p> <p>4 consumers regarding generic drugs generally</p> <p>5 as a therapeutic option or class?</p> <p>6 MR. GOLDBERG: Objection to</p> <p>7 form. Ambiguous.</p> <p>8 A. Can you give me an example of</p> <p>9 what that messaging would look like so I'm</p> <p>10 better able to understand?</p> <p>11 BY MR. DAVIS:</p> <p>12 Q. Sure.</p> <p>13 MR. DAVIS: I'm handing to be</p> <p>14 marked as Exhibit 4 a 14-page</p> <p>15 document.</p> <p>16 (Whereupon, Keller Exhibit</p> <p>17 Number 4 was marked for</p> <p>18 identification.)</p> <p>19 MR. HONIK: Is this 16, John?</p> <p>20 MR. DAVIS: Yes.</p> <p>21 MS. ANDRAS: Can you describe</p> <p>22 for the record for counsel who do not</p> <p>23 have copies of these what document</p> <p>24 you've marked?</p>	<p style="text-align: right;">Page 81</p> <p>1 a sort of general resource put out by the FDA</p> <p>2 titled "Generic Drugs: Questions & Answers"?</p> <p>3 A. That's what the title says,</p> <p>4 yes.</p> <p>5 Q. And it has some subsections</p> <p>6 like, "What are generic drugs? How does the</p> <p>7 FDA ensure generic medicines work the same as</p> <p>8 brand-name medicines?"</p> <p>9 Do you see that?</p> <p>10 A. I see that on the first page,</p> <p>11 but I have not had a chance to review this</p> <p>12 document, so...</p> <p>13 Q. Well, I only provided this as</p> <p>14 an example.</p> <p>15 So as an example of what I was</p> <p>16 talking about prior to showing you this</p> <p>17 document, have you reviewed or had any</p> <p>18 occasion to review any kind of general</p> <p>19 resources similar to the one that I've marked</p> <p>20 as Exhibit 4 that have to do with generic</p> <p>21 drugs generally?</p> <p>22 A. I cannot answer that question</p> <p>23 about how -- whether I've reviewed anything</p> <p>24 similar without knowing what this is to make</p>

<p style="text-align: right;">Page 82</p> <p>1 that comparison. I need time to review this 2 document. 3 Q. Okay. 4 (Witness reviewing document.) 5 MR. GOLDBERG: Dr. Keller, if 6 you're going to go further, we can go 7 off the record for a minute until you 8 finish, okay? That's fine. 9 Can we go off the record? 10 THE VIDEOGRAPHER: Off record 11 at 11:25. 12 (Off the record.) 13 THE VIDEOGRAPHER: Back on the 14 record at 11:30. 15 BY MR. DAVIS: 16 Q. Okay. Dr. Keller, you had a 17 chance to flip through every page of that 18 document, correct? 19 A. Yes. 20 Q. Okay. And you read it, you 21 didn't just flip the pages? 22 A. I, I'm going to use the word 23 surveyed, or looked broadly over would be a 24 better term for it. I tried -- it was not a</p>	<p style="text-align: right;">Page 84</p> <p>1 now, would you agree that the basic message 2 that's being put out by the FDA is that 3 generic drugs are just as safe, effective, 4 and high quality as their brand name 5 counterparts? 6 MR. DAVIS: Could you repeat 7 the question? 8 (Whereupon, the reporter read 9 back the following: 10 QUESTION: Having looked at it 11 now, would you agree that the basic 12 message that's being put out by the 13 FDA is that generic drugs are just as 14 safe, effective, and high quality as 15 their brand name counterparts?) 16 A. Yes, from -- more true, yes, 17 from the FDA's perspective. No, that would 18 not be my uniform takeaway from a consumer 19 perspective. 20 BY MR. DAVIS: 21 Q. Well, what's unclear about the 22 first page, the little graphic that the FDA 23 provides, where it says "Generic, Safe, 24 Effective, High-Quality" all with checkmarks,</p>
<p style="text-align: right;">Page 83</p> <p>1 lot of time. I tried to look at it as 2 carefully as I could. 3 Q. Okay. Have you ever seen a -- 4 you see that this is a Q&A titled "Generic 5 Drugs: Questions & Answers"? 6 A. Yes. 7 Q. Have you ever seen a Q&A or an 8 FAQ document in any context? 9 A. Yes. 10 Q. And this is an example of one 11 of those, but for generic drugs, put out by 12 the FDA, correct? 13 A. Yes. 14 Q. Okay. Would you characterize 15 this as an educational resource having looked 16 at it? 17 A. You need to be more specific. 18 What does "educational resource" mean? 19 Q. Well, for example, did you -- 20 in reading it, were you able to educate 21 yourself a little bit on generic drugs? 22 A. Yes. 23 Q. Okay. Thank you. 24 Is the -- having looked at it</p>	<p style="text-align: right;">Page 85</p> <p>1 "Brand-Name, Safe, Effective, High-Quality," 2 all with checkmarks? 3 Do you see that? 4 A. Yes. 5 Q. Okay. And the message that the 6 FDA is trying to convey is that generic drugs 7 are just as safe, effective, and high quality 8 as their brand name counterparts. Is that 9 not the message the FDA is trying to convey 10 here? 11 A. You are correct that those 12 checkmarks appear on the first page. But 13 when I read the information on subsequent 14 pages, as I read information such as The 15 generic may act differently from the brand 16 name, for example, in absorption. 17 Q. So you disagree that the FDA is 18 attempting to convey a message here that 19 generic drugs and brand name drugs are 20 interchangeable? 21 A. No. 22 MR. GOLDBERG: Objection to 23 form. 24 A. Please specify.</p>

<p style="text-align: right;">Page 86</p> <p>1 BY MR. DAVIS:</p> <p>2 Q. Okay. Well, let's start with</p> <p>3 my prior question.</p> <p>4 You agree, yes, that the FDA's</p> <p>5 intended message with this document, and</p> <p>6 specifically with this graphic on the first</p> <p>7 page, is that generic drugs are just as safe,</p> <p>8 effective, and high quality as their brand</p> <p>9 name counterparts?</p> <p>10 A. Incorrect. I said that the</p> <p>11 graphic displays that. But if you said the</p> <p>12 document, which I'm assuming you're referring</p> <p>13 to the document before me, that that has</p> <p>14 information in there, and I gave you only one</p> <p>15 example from my quick read or survey of the</p> <p>16 information that led me to believe that they</p> <p>17 are not the same.</p> <p>18 For example, on effectiveness,</p> <p>19 I just told you that I read that the</p> <p>20 absorption for generics may be different from</p> <p>21 brand products, brand name products.</p> <p>22 Q. Do you know what "absorption"</p> <p>23 means?</p> <p>24 A. Again, I need to look at the</p>	<p style="text-align: right;">Page 88</p> <p>1 Q. And then it reads further down</p> <p>2 that part of that is ensuring, last two</p> <p>3 lines, "that every generic drug is safe,</p> <p>4 effective, high quality, and substitutable to</p> <p>5 the brand name drug."</p> <p>6 Do you see that?</p> <p>7 A. I do not, sorry. Where is</p> <p>8 that?</p> <p>9 Q. That would be the last two</p> <p>10 lines of the first paragraph.</p> <p>11 A. Oh, the last two lines, okay.</p> <p>12 I went to the bottom of the page.</p> <p>13 Yes, I see that.</p> <p>14 Q. Okay. And so the FDA is</p> <p>15 essentially stating in text there what it</p> <p>16 stated in the graphic on the first page,</p> <p>17 correct?</p> <p>18 A. I do not view them the same.</p> <p>19 Q. What's different to you?</p> <p>20 A. So for me, when I see a graphic</p> <p>21 with the checkmarks, the checkmarks look the</p> <p>22 same, and it appears to be the same for</p> <p>23 generic and brand name.</p> <p>24 But when I look at the text</p>
<p style="text-align: right;">Page 87</p> <p>1 document.</p> <p>2 Q. Well, why don't I take you to</p> <p>3 page 12 of the document. Do you see the</p> <p>4 heading "How Does FDA monitor side effects or</p> <p>5 safety issues with generic medicines?" Do</p> <p>6 you see that heading on page 12?</p> <p>7 A. Before I answer that, can I</p> <p>8 assume when you ask a different question</p> <p>9 without my answering the previous one that</p> <p>10 you are striking it?</p> <p>11 Q. Sure. Yeah. I'm moving on.</p> <p>12 A. Okay.</p> <p>13 Q. I might come back to it.</p> <p>14 So do you see the header there</p> <p>15 on page 12?</p> <p>16 A. "How Does FDA monitor side</p> <p>17 effects or safety issues with generic</p> <p>18 medicines?"</p> <p>19 Q. It says there that the "FDA</p> <p>20 takes several actions to ensure safety and</p> <p>21 quality before and after a new or generic</p> <p>22 medicine is approved."</p> <p>23 Do you see that?</p> <p>24 A. Yes.</p>	<p style="text-align: right;">Page 89</p> <p>1 here, the text that you asked -- that you</p> <p>2 referred to for this question, when it says</p> <p>3 that the word "to ensure" is not telling --</p> <p>4 they're saying they're trying their best,</p> <p>5 that's my interpretation of "ensure," but</p> <p>6 that does not mean that they are, for</p> <p>7 example, in a marketing context doing</p> <p>8 something more, like saying it is the same.</p> <p>9 Q. Well, they're not saying</p> <p>10 anything about trying their best here,</p> <p>11 they're saying that they "ensure that every</p> <p>12 generic drug is safe, effective, high</p> <p>13 quality, and substitutable to the brand name</p> <p>14 drug." They say that right there, correct?</p> <p>15 A. They say that. You asked me</p> <p>16 why I didn't think it was the same in the</p> <p>17 graphic and the document, and I'm telling you</p> <p>18 that it appears to me to be the same, brand</p> <p>19 and generic on those three features in the</p> <p>20 graphic, but not in the document.</p> <p>21 And the reason it is not for me</p> <p>22 the same in the document is because of the</p> <p>23 language that is used here, specifically in</p> <p>24 this particular case in the sentence you</p>

<p>Page 90</p> <p>1 asked me to read on ensure, that makes me</p> <p>2 believe that it may not be the same, or that</p> <p>3 FDA is doing something to ensure that it is</p> <p>4 the same, but it's not saying it is the same.</p> <p>5 Q. Okay. Do you know what would</p> <p>6 happen, for example, if the FDA, despite</p> <p>7 their best efforts, found out that a generic</p> <p>8 drug was not safe, not effective, or not high</p> <p>9 quality? Do you know what would happen in</p> <p>10 that case?</p> <p>11 A. I'm not an expert. I cannot</p> <p>12 tell you for sure.</p> <p>13 Q. Okay. Go to page 2 of the</p> <p>14 document, if you don't mind.</p> <p>15 A. The same document?</p> <p>16 Q. Same document. Exhibit 4 for</p> <p>17 the record.</p> <p>18 That first question there that</p> <p>19 appears in this Q&A is, "What are generic</p> <p>20 drugs?"</p> <p>21 Do you see that?</p> <p>22 A. Yes.</p> <p>23 Q. And it says, "A generic drug is</p> <p>24 a medication created to be the same as an</p>	<p>Page 92</p> <p>1 So you're referring to the last</p> <p>2 sentence, "In other words, you can take a" --</p> <p>3 yes, I see that, yes.</p> <p>4 Q. And the "you" there is the</p> <p>5 patient, correct, the consumer?</p> <p>6 A. The consumer for whom this</p> <p>7 medicine is applicable, right.</p> <p>8 Q. And to borrow some terminology</p> <p>9 you used before, this would be the advocated</p> <p>10 recommendation, correct, by the FDA regarding</p> <p>11 generic drugs?</p> <p>12 A. Yes and no. Yes if this</p> <p>13 document was defined as a communication</p> <p>14 message to consumers; no because it's not</p> <p>15 clear to me what the specific advocated</p> <p>16 action is.</p> <p>17 Q. What makes you think that this</p> <p>18 might not be a document directed to</p> <p>19 consumers?</p> <p>20 A. I don't know. I don't know the</p> <p>21 context in which this was created, or when it</p> <p>22 was created, and for whom it was intended. I</p> <p>23 don't have that information.</p> <p>24 Q. You can't derive that from</p>
<p>Page 91</p> <p>1 already marketed brand-name drug in dosage</p> <p>2 form, safety, strength, route of</p> <p>3 administration, quality, performance</p> <p>4 characteristics, and intended use."</p> <p>5 And then if you go down to the</p> <p>6 last sentence you'll see, "In other words,</p> <p>7 you can take a generic medicine as an equal</p> <p>8 substitute for its brand-name counterpart."</p> <p>9 Do you see that?</p> <p>10 A. Yes.</p> <p>11 Q. Okay. Who is the "you" there</p> <p>12 in this document? Who do you imagine the FDA</p> <p>13 is referring to as "you" here?</p> <p>14 A. Whoever is reading the message.</p> <p>15 Q. Or whoever is taking the</p> <p>16 generic medicine, as they say, correct? "You</p> <p>17 can take a generic medicine."</p> <p>18 A. No. It says you can take it.</p> <p>19 It doesn't mean they're taking it.</p> <p>20 Q. Do you read "you" here as being</p> <p>21 directed to the consumer, the person who</p> <p>22 takes the generic medicine?</p> <p>23 A. I need to look at the document</p> <p>24 again.</p>	<p>Page 93</p> <p>1 having just read this?</p> <p>2 A. As a health communication</p> <p>3 expert, I would not like to make that</p> <p>4 determination.</p> <p>5 Q. Okay. Well, you did agree with</p> <p>6 me earlier that the "you" in that sentence</p> <p>7 was directed towards the consumer or patient,</p> <p>8 correct?</p> <p>9 A. I said that it was directed at</p> <p>10 a person for whom a decision about a generic</p> <p>11 or brand name selection was applicable.</p> <p>12 Q. And that would be a consumer or</p> <p>13 a patient, correct?</p> <p>14 A. If a consumer was considering</p> <p>15 whether -- what the difference was, they</p> <p>16 might or might not seek this information.</p> <p>17 There would be a range.</p> <p>18 Q. And that advocated</p> <p>19 recommendation there that we read, "you can</p> <p>20 take a generic medicine as an equal</p> <p>21 substitute for its brand-name counterpart,"</p> <p>22 that's founded on the assumption that the</p> <p>23 generic drug and the brand-name drug are both</p> <p>24 safe, effective, and high quality, and</p>

<p>Page 94</p> <p>1 substitutable as we saw on page 12 that we 2 just read, correct? 3 MR. GOLDBERG: Objection to 4 form. Foundation. 5 A. That is not how I interpret 6 that. 7 BY MR. DAVIS: 8 Q. What's incorrect about my 9 interpretation? 10 A. I'll highlight one. 11 Q. Sure. 12 A. First, very simply, this 13 information appears before page 12, so I 14 don't know whether this was based on what is 15 in page 12, especially if it appears before. 16 I'll stop there. 17 Q. Okay. Well, I mean, what about 18 what appears just before the sentence on 19 page 2, "A generic drug is a medication that 20 is created to be the same as an already 21 marketed brand-name drug in dosage form, 22 safety, strength, route of administration, 23 quality, performance characteristics, 24 intended use," those various things, do you</p> <p>Page 95</p> <p>1 think safety, efficacy, and high quality are 2 encompassed by those terms in that sentence? 3 A. No. 4 Q. You don't? 5 A. No. 6 Q. Okay. Explain to me why not. 7 A. From -- as a consumer expert, 8 consumer health decision-making expert, one 9 example would be that for me, efficacy is 10 broken down into self efficacy and response 11 efficacy. 12 Response efficacy is, you know, 13 does the drug do what it's supposed to do; 14 self efficacy is, you know, will the drug 15 work for me. 16 Q. Okay. You testified earlier 17 that you have very little knowledge of what's 18 required for drug approval in the US, 19 correct? 20 A. Yes. 21 Q. Okay. So you really don't know 22 what the FDA means by "efficacy" in terms of 23 approval of a brand or generic drug, is that 24 correct?</p>	<p>Page 96</p> <p>1 A. Actually please repeat that 2 question. 3 MR. DAVIS: Can you read the 4 question back? 5 (Whereupon, the reporter read 6 back the question: 7 QUESTION: Okay. So you really 8 don't know what the FDA means by 9 "efficacy" in terms of approval of a 10 brand or generic drug, is that 11 correct?) 12 A. I'm not going to form an 13 opinion on that. 14 BY MR. DAVIS: 15 Q. Okay. You're a health 16 communication expert, correct? 17 A. I'm an expert on consumer 18 decision-making with a focus on health. 19 Q. In fact, you testified today 20 that you've designed some of the content of 21 the messages to consumers, correct? 22 A. The content of some of the 23 health communication to consumers. 24 Q. Correct.</p> <p>Page 97</p> <p>1 And having just leafed through 2 this document here, Exhibit 4, using your -- 3 you know, relying on your expertise as 4 someone who does this for a living, what is 5 the message that the FDA is trying to impart 6 with this Q&A document that's Exhibit 4? 7 A. There's a lot of information 8 here. I would not be comfortable telling you 9 what the FDA's intentions are or what they 10 are trying to impart. 11 Q. You don't think they're trying 12 to impart to a consumer or patient that they 13 can take a generic medicine as an equal 14 substitute for its brand-name counterpart? 15 A. I've tried to answer that 16 question. As a communication expert, I'm 17 leery of any sentence that starts with "in 18 other words." 19 Q. Aren't they -- I mean, the in 20 other words to me is the FDA trying to take a 21 complex regulatory system of drug approval 22 and put it in simple terms for a patient or 23 consumer. Do you not read it that way? 24 A. I do not, because I'm putting</p>
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<p style="text-align: right;">Page 98</p> <p>1 on my consumer hat, and I see a lot of things 2 here that -- route of administration, 3 etcetera -- that are not -- may not be 4 familiar to some consumers, they may be 5 familiar to other consumers, but I'm going to 6 predict a range of what consumers take away 7 from that message. 8 Q. Flip to page 6. You'll see 9 some pagination in the bottom right corner of 10 page 6 of 14. The header there is "What 11 standards must generic medicines meet to 12 receive FDA approval?" 13 Do you see that? 14 A. Yes. 15 Q. Okay. And I think you 16 testified earlier that you didn't know what 17 an ANDA was. I'll represent to you that an 18 ANDA is an Abbreviated New Drug Application, 19 which is what a generic manufacturer submits 20 to the FDA for approval of its proposed 21 generic medicine to be marketed in the US. 22 Do you understand that? 23 A. I see here it says "drug 24 companies," it does not say "generic</p>	<p style="text-align: right;">Page 100</p> <p>1 that that was a requirement for ANDA approval 2 of a generic drug to be marketed in the US? 3 A. I saw that in Dr. Conti's 4 report. 5 Q. Do you have any reason to 6 disagree with what's in this bullet point 7 here -- 8 A. NO. 9 Q. -- on page 7? 10 Let's say that the FDA, that 11 you've worked -- strike that. 12 You've worked with regulatory 13 bodies in the US, correct, like, for example, 14 the CDC? 15 A. Yes. 16 Q. Okay. Let's say that the FDA 17 came to you and said, Dr. Keller, we've 18 noticed that consumers/patients in the US, 19 there's a distrust for generic medicines, we 20 want you to design a messaging campaign to 21 advocate -- to create an advocated 22 recommendation that patients can trust their 23 generic drugs. 24 Are you following me?</p>
<p style="text-align: right;">Page 99</p> <p>1 manufacturers." But I see the rest. 2 Q. Well, I'll represent to you 3 that an ANDA, or A-N-D-A, Abbreviated New 4 Drug Application is what a generic 5 manufacturer submits to market a generic 6 drug, okay? And then it says below that, "An 7 ANDA must show the generic medicine is 8 equivalent to the brand in the following 9 ways:" 10 Do you see that? 11 A. Yes. 12 Q. And then there's some bullet 13 points that start on 6, go down to 7 and 8, 14 and conclude on page 9, I believe. 15 Do you see that? 16 A. Yes. 17 Q. Okay. If you flip to page 7, 18 you'll see that the last bullet point there 19 says that "It" -- being the generic drug -- 20 "is manufactured under the same strict 21 standards as the brand-name medicine." 22 Do you see that? 23 A. Yes. 24 Q. Okay. Did you have any idea</p>	<p style="text-align: right;">Page 101</p> <p>1 A. Mm-hmm. 2 Q. Okay. Would not one of the 3 messages you would include in that advocated 4 recommendation to patients, would not one of 5 those messages be exactly what the FDA is 6 emphasizing here, which is that generic drugs 7 are subject to -- are substitutable as we saw 8 on page 12, that they are safe, effective, 9 high quality as we saw on page 1, and that 10 they are manufactured under the same strict 11 standards as the brand-name medication as we 12 see on page 7? 13 Would those not be messages you 14 might want to include in your communication 15 to patients to overcome that objection to 16 generic drugs? 17 MR. GOLDBERG: Objection. 18 Ambiguous, compound. 19 A. I don't know how -- I stopped 20 counting how many questions there were in 21 that question. Could you please break it 22 down? 23 BY MR. DAVIS: 24 Q. I mean, I thought it was quite</p>

<p style="text-align: right;">Page 102</p> <p>1 clear, to be honest.</p> <p>2 Would you not want to include</p> <p>3 those messages that we've called out and read</p> <p>4 in this document in your advocated</p> <p>5 recommendation to consumers that the FDA in</p> <p>6 this hypothetical assignment is giving you?</p> <p>7 MR. GOLDBERG: Same objection.</p> <p>8 A. I cannot answer that question.</p> <p>9 I was even flipping pages, and I'm on</p> <p>10 page 12, and I cannot in my quick survey even</p> <p>11 find the word "substitutable," so I cannot</p> <p>12 answer that question.</p> <p>13 BY MR. DAVIS:</p> <p>14 Q. We read it. It's the last</p> <p>15 sentence of the first paragraph there.</p> <p>16 "Ensure that every generic drug is safe,</p> <p>17 effective, high quality, and substitutable to</p> <p>18 the brand-name drug."</p> <p>19 A. Thank you.</p> <p>20 Q. Would you not want to include</p> <p>21 those messages that we've read in this</p> <p>22 document just now in your communication to</p> <p>23 consumers/patients in this hypothetical</p> <p>24 assignment from the FDA?</p>	<p style="text-align: right;">Page 104</p> <p>1 communication and what kind of costs I need</p> <p>2 to address or overcome in the communication.</p> <p>3 My research shows that these</p> <p>4 factors vary across individuals, and all of</p> <p>5 my work and my report supports, along with</p> <p>6 many, many others, the need to get this</p> <p>7 information in order to tailor this</p> <p>8 communication so that I can understand how</p> <p>9 consumers would evaluate my advocated</p> <p>10 recommendation, "my" as in my task.</p> <p>11 Q. Do you think there's a single</p> <p>12 consumer out there in the US who if they went</p> <p>13 to the pharmacy and got dispensed a generic</p> <p>14 drug, that they would not want that generic</p> <p>15 drug to be substitutable to the brand-name</p> <p>16 drug?</p> <p>17 A. As a consumer behavior expert,</p> <p>18 you never want to make an assumption about</p> <p>19 uniformity on consumer reactions or</p> <p>20 valuations of work.</p> <p>21 Q. So are you saying that you</p> <p>22 think it's a possibility that there are</p> <p>23 consumers out there who, when they went to</p> <p>24 the pharmacy to fill a prescription and they</p>
<p style="text-align: right;">Page 103</p> <p>1 A. If the FDA came to me with this</p> <p>2 assignment, I would need a lot of information</p> <p>3 on consumers to make a decision about the</p> <p>4 different types of effective -- the different</p> <p>5 types of messages that may be effective for</p> <p>6 different types of consumers based on -- I'll</p> <p>7 just give you examples because it was a long</p> <p>8 question -- where and how and from whom they</p> <p>9 would trust the message, or message factors,</p> <p>10 I'm using MICI, their individual differences,</p> <p>11 for example education level, language</p> <p>12 fluency, etcetera; the context in which they</p> <p>13 were making this decision, for example with a</p> <p>14 trusted physician or a new physician; and the</p> <p>15 interaction of those factors.</p> <p>16 I would also want to know</p> <p>17 information on the features that patients</p> <p>18 take into account when they're making such a</p> <p>19 decision.</p> <p>20 I testified earlier about</p> <p>21 the -- how I create communication to create</p> <p>22 and communicate value to consumers, so I</p> <p>23 would need to know what kind of benefits</p> <p>24 different consumers are seeking in the</p>	<p style="text-align: right;">Page 105</p> <p>1 got dispensed the generic drug, that they</p> <p>2 would not want that generic drug to be</p> <p>3 substitutable to the brand-name drug?</p> <p>4 A. I'm going to say yes and no.</p> <p>5 I will say yes, they will</p> <p>6 expect that they are getting something from</p> <p>7 the pharmacy that the pharmacist or someone</p> <p>8 else who made the decision believes is</p> <p>9 similar.</p> <p>10 No as in they don't know</p> <p>11 whether it would be similar for them because</p> <p>12 they don't -- they have more information and</p> <p>13 agency on what has worked for them in the</p> <p>14 past, what has not worked for them in the</p> <p>15 past, the individual factors that I'm talking</p> <p>16 about, how they take their medication, you</p> <p>17 can't make an assumption, you know, are they</p> <p>18 used to taking it once a day, multiple times</p> <p>19 a day, whether they take it with food,</p> <p>20 without food.</p> <p>21 There are so many additional</p> <p>22 factors where they would have questions about</p> <p>23 similarity or substitutability, because from</p> <p>24 a consumer behavior perspective it's not what</p>

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1 someone else is saying is similar, it's how
2 they're experiencing similarity, or if their
3 experience is the same.
4 Q. If a generic drug were not
5 substitutable to the brand-name drug, do you
6 have any idea whether that would be a
7 non-approved drug?
8 A. I am not familiar with the FDA
9 regulations, so I cannot answer that
10 question.
11 Q. Have you ever designed any kind
12 of messaging to consumers or physicians that
13 advocated that they take or prescribe
14 unapproved medications?
15 A. No.
16 Q. Have you ever designed any kind
17 of messaging to consumers or physicians that
18 they take or prescribe adulterated
19 medications?
20 A. Not to my knowledge.
21 Q. Misbranded medications?
22 A. Please define "misbranded."
23 Q. Do you know what misbranded
24 means?

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1 A. From Dr. Conti's report I have
2 a general understanding.
3 Q. And what's that understanding?
4 A. That the -- what is in the
5 brand -- in the product is not the same as
6 what is on the description.
7 Q. Right. That the label is false
8 or misleading in any particular, correct?
9 A. Well, no, I will not go that
10 far. I will not say the label is false or
11 misleading. That will vary by the consumer.
12 Q. Well, you don't know whether
13 that's, in fact, the definition that congress
14 provides for misbranding.
15 A. Agreed, I'm not an expert.
16 Q. Okay. Have you ever designed
17 any kind of communication or messaging to
18 physicians or consumers that they take or use
19 any kind of medication that was illegally
20 sold or distributed to them?
21 A. Not that I'm aware of.
22 MR. DAVIS: I'm at a transition
23 point. Do we want to take lunch, or
24 do you want to keep going?

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1 MR. GOLDBERG: Up to you. I
2 know lunch is here.
3 THE WITNESS: I'm indifferent.
4 MR. DAVIS: Why don't we go off
5 the record for a second.
6 THE VIDEOGRAPHER: Off the
7 record at 12:01.
8 (Whereupon, a luncheon recess
9 was taken.)
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1 AFTERNOON SESSION
2
3 THE VIDEOGRAPHER: Back on the
4 record at 12:40.
5 BY MR. DAVIS:
6 Q. Okay. Dr. Keller, your report,
7 Exhibit 2, would you mind pulling that out?
8 I want to ask you --
9 A. You mean Appendix B?
10 Q. No, no, just your report, which
11 is -- I've marked as Exhibit 2.
12 A. I'm so sorry. I misunderstood.
13 Q. Not a problem.
14 So I just want to ask a
15 clarifying question regarding your assignment
16 on paragraph 1, which is on the first page.
17 You say, "I have been asked by
18 counsel for Defendants to review health care
19 decision-making and how valuation of VCDs
20 should be viewed in light of the voluntary
21 recall of VCDs in 2018 and '19."
22 Are you with me there?
23 A. Yes.
24 Q. Okay. I'm just trying to

<p style="text-align: right;">Page 110</p> <p>1 understand the word "and" there. Is that two 2 assignments, or is that one assignment? 3 A. I'd say that the assignments 4 are connected. 5 Q. Okay. And what do you mean by 6 that? 7 A. That I reviewed the healthcare 8 decision-making literature to help inform my 9 opinion on how consumers -- the range of 10 consumer responses for those taking the VCDs, 11 how they might respond, if at all, to the 12 recall of the VCDs in 2018 and 2019. 13 Q. Okay. So when you say 14 healthcare decision-making there, you're 15 referring to the portion of your report 16 discussing and setting forth compensatory 17 decision analysis and noncompensatory, and 18 non-MICI, that acronym, that's what you mean 19 by healthcare decision-making? 20 A. Could you please repeat that 21 question? 22 Q. Sure. I'm just trying to 23 connect your assignment to the substance of 24 your report.</p>	<p style="text-align: right;">Page 112</p> <p>1 assignment to what's in your report. 2 And so you reviewed healthcare 3 decision-making as a general proposition from 4 a consumer and physician standpoint, correct? 5 A. Yes. 6 Q. Okay. And that's discussed in 7 sort of your general outline of compensatory 8 and noncompensatory decision rules and MICI, 9 correct? 10 A. Yes. 11 Q. Okay. And then you applied 12 that framework to the facts of this case, or 13 attempted to, correct? 14 A. No, to perform my task that you 15 just highlighted in the first paragraph. 16 Q. So are you telling me you did 17 not apply that framework to -- or attempt to 18 apply that framework to the facts of this 19 case? 20 A. I didn't say that. I think I 21 said just the opposite. 22 Q. Well, that's what I was asking 23 you to confirm, and you wouldn't confirm it. 24 A. Yes.</p>
<p style="text-align: right;">Page 111</p> <p>1 So when you say you've been 2 asked by counsel for defendants to review 3 healthcare decision-making, am I to 4 understand the healthcare decision-making 5 there to refer to the portion of your report 6 that discusses the compensatory decision rule 7 and noncompensatory decision rule that you 8 explain in your report, as well as the MICI 9 factors? 10 A. Yes and no. The yes is that I 11 have reviewed the literature on the 12 compensatory/noncompensatory decision rules, 13 and reported a subset of that literature as 14 well as the MICI framework, but not just for 15 the -- how consumers might react to the 16 recall of the VCDs in question, because 17 there's a second part of the paragraph, which 18 I also reviewed the literature to evaluate 19 from a consumer's perspective Dr. Conti's 20 claim, in particular that the VCDs at issue 21 were worthless to consumers as a result of 22 the recall. 23 Q. Well, and I'm -- we'll get to 24 that. I'm just trying to connect your</p>	<p style="text-align: right;">Page 113</p> <p>1 Q. So let me rephrase it so we're 2 on the same page. 3 You then applied the 4 compensatory/noncompensatory decision rule 5 analysis and MICI to the facts of this case, 6 correct? 7 A. I would not go so far as to the 8 facts of this case. There are many facts of 9 this case that I -- that are not part of my 10 task. 11 Q. So are you saying you did not 12 apply -- what did you -- let me ask it this 13 way. 14 What did you apply those 15 healthcare decision-making concepts that you 16 outlined? What did you apply those to? 17 A. The 18 compensatory/noncompensatory rules for how 19 consumers make a value judgment based on the 20 alternatives they consider, the weights of 21 the different attributes they consider, and 22 the ratings that they give to those 23 attributes in different combinations, and the 24 MICI factors were used by me or applied by me</p>

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1 to make an assessment of how consumers might
 2 respond to the recall -- to the recall VCDs,
 3 and to answer the question would all
 4 consumers uniformly believe that the recall
 5 VCDs were worthless.
 6 Q. You're not a physician, are
 7 you?
 8 A. No.
 9 Q. Okay. And you're not a public
 10 health official?
 11 A. Define "public health
 12 official."
 13 Q. Like you don't work for the FDA
 14 or the CDC, or you're not a public health
 15 official, are you?
 16 A. I am not a full-time employee
 17 of a government agency.
 18 Q. Okay. And you wouldn't hold
 19 yourself out as being an expert on the
 20 substance of any medical decisions,
 21 treatments, that a physician might make or
 22 the FDA might recommend, correct?
 23 A. Please define "substance."
 24 Q. Sure.

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1 You wouldn't be -- you wouldn't
 2 step into the role of a physician and say --
 3 to tell consumers do this or don't do this
 4 from a medical standpoint, would you?
 5 A. Please define "from a medical
 6 standpoint."
 7 Q. Exactly what physicians do
 8 every day when they talk to their patients,
 9 you wouldn't step into that role, would you?
 10 A. As shown in my report, and one
 11 recent project comes to mind, I provide
 12 communication strategies for physicians to
 13 tailor their messages and recommendations to
 14 their patients.
 15 Q. But you wouldn't come up with
 16 the recommendation itself; you're coming up
 17 with the messaging around that
 18 recommendation, correct?
 19 A. I'm having a hard time
 20 separating some of those, or trying to
 21 understand what you're getting at.
 22 Q. It's a simple question.
 23 You don't practice medicine, do
 24 you?

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1 A. No.
 2 Q. And as far as the medical
 3 substance of medical care, you don't step
 4 into the role of the physician and actually
 5 advocate of your own accord treatment
 6 decisions, do you?
 7 A. No.
 8 Q. Okay. And same thing for --
 9 same question for public health officials,
 10 you don't substitute your judgment for that
 11 of the regulator, for example the FDA, in any
 12 of the decisions that are within its
 13 regulatory ambit, do you?
 14 MR. GOLDBERG: Objection to
 15 form. Ambiguous.
 16 A. I'm not clear on the question.
 17 BY MR. DAVIS:
 18 Q. Okay. I mean, I asked a
 19 variation of that question right before
 20 lunch, which was, you would never advocate in
 21 any message that physicians take or a
 22 patient -- physicians prescribe or patients
 23 take unapproved medications, for example,
 24 would you?

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1 A. I do not recall that question,
 2 so...
 3 Q. Well, let me ask that question
 4 again.
 5 Would you ever advocate in any
 6 kind of health communication messaging that a
 7 physician prescribe an unapproved medication?
 8 MR. GOLDBERG: Objection to
 9 form.
 10 A. Please repeat that.
 11 MR. DAVIS: Can you read the
 12 question back?
 13 (Whereupon, the reporter read
 14 back the question:
 15 QUESTION: Would you ever
 16 advocate in any kind of health
 17 communication messaging that a
 18 physician prescribe an unapproved
 19 medication?)
 20 MR. GOLDBERG: Objection to
 21 form. Ambiguous.
 22 A. Unapproved by?
 23 BY MR. DAVIS:
 24 Q. You understand that drugs have

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1 to be pre-approved, correct?

2 A. So I just want to make sure

3 that this is not unapproved by the physician

4 or somebody else. I just want to be clear.

5 Q. Yes. When I say "unapproved

6 medication," I'm talking about FDA approval

7 that's required for all drug products in the

8 US.

9 So the question is, would you

10 ever in any of your health communication

11 messaging advocate for the use of an

12 unapproved medication?

13 A. In this particular case I have

14 reviewed and included in my report materials

15 where physicians continued to ask -- to

16 recommend to their patients that they take a

17 VCD that was recalled.

18 Q. That's not answering my

19 question.

20 A. So if I -- you said are there

21 any circumstances. So just like your

22 previous hypothetical that if the FDA asked

23 me to create a communication, if a physician

24 asked me to create a communication I would

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1 not -- I would try to say no, I'm not going

2 to do that because the FDA has not approved

3 this communication. And that's why I gave

4 you the example I did.

5 If there is some understanding

6 that they should continue to take the

7 medication, then I would help them do that.

8 Q. Well, I'm not -- you're not

9 following the thrust of my question. I'm

10 asking you about --

11 A. Sorry.

12 Q. -- a drug that was never

13 approved.

14 A. Oh, I'm sorry, I didn't hear

15 never approved.

16 Q. That's what I mean by

17 "unapproved medication," something that

18 wasn't approved.

19 So would you ever advocate --

20 and this gets to my broader question about

21 you not substituting your judgment or making

22 any kind of public health judgments that are

23 preserved for the regulator, correct? And

24 the question is, would you ever advocate for

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1 the use of an unapproved drug? And by that I

2 mean something that was never approved by the

3 FDA.

4 MR. GOLDBERG: Objection to

5 form. Ambiguous, speculative.

6 A. I don't ask those questions.

7 There is a review process for the work that I

8 do, and I leave it to others to make those

9 determinations.

10 I have a very specific role

11 that I play in designing the message

12 communication, and that role does not require

13 any expertise or knowledge on my part on

14 regulatory approval or unapproved or anything

15 of that spectrum.

16 Q. Right. And that's simply my

17 question, is you rely on those people to do

18 their job, right? You rely on the FDA to do

19 the business of public health regulation,

20 correct?

21 A. That is not what I said. You

22 asked me in my projects, in all my previous

23 work, you know, do I -- this is my

24 understanding of what you asked me, do I

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1 ensure, or do I seek information or -- sorry,

2 I'm sorry, it was dinging away and I

3 didn't --

4 MR. GOLDBERG: Can we just go

5 off the record for a second?

6 THE VIDEOGRAPHER: Off record

7 at 12:54.

8 (Off the record.)

9 THE VIDEOGRAPHER: Back on at

10 12:54.

11 A. So I agree that that was not my

12 job on these projects. I'm not agreeing that

13 it's the FDA's job. I'm saying, depending on

14 the project, I don't know who takes care of

15 different aspects of the job.

16 BY MR. DAVIS:

17 Q. Let me ask it this way.

18 Have you ever designed any kind

19 of messaging that's health-related to

20 consumers or physicians that you knew was

21 inconsistent with what the FDA's position was

22 on that very subject?

23 A. I have never checked to see

24 whether what I'm designing a message -- a

<p style="text-align: right;">Page 122</p> <p>1 health message for has or has not been 2 approved by the FDA. 3 Q. Well, I'm not saying approved 4 by the FDA. I'm saying, have you ever done 5 that, have you ever designed a message 6 related to healthcare that goes out to a 7 consumer or physician that you knew was 8 inconsistent with the FDA's position on that 9 very same subject matter? 10 A. I'm not an expert on the FDA, 11 and that is not something that I would seek 12 or look for information on before I designed 13 the message. 14 Q. Okay. You wouldn't hold 15 yourself out as an expert on how to 16 appropriately address from a medical care 17 standpoint a patient who was taking 18 nitrosamine-contaminated VCDs, would you? 19 A. Please repeat that question. 20 Q. You wouldn't hold yourself out 21 as an expert on the medical care decisions 22 that a physician and patient may want to make 23 in response to a patient's exposure to 24 nitrosamines in their valsartan, would you?</p>	<p style="text-align: right;">Page 124</p> <p>1 form. Ambiguous. 2 A. I don't know what those 3 structural elements are, and I'm not an 4 expert on what congress and the FDA have -- 5 the system that they've created, and I'm not 6 going to give you an opinion on that. 7 BY MR. DAVIS: 8 Q. Right. 9 And you're not taking any issue 10 with any of that is my question, correct? 11 A. I'm -- if I'm not an expert on 12 it and I'm not giving an opinion on it, I 13 should not be interpreted as taking issue 14 with it. I have nothing to say about it. 15 Q. Okay. You -- continuing in 16 that assignment paragraph, you say you've 17 been tasked with evaluating certain 18 assertions from Dr. Conti, particularly her 19 claim that VCDs in this case were worthless. 20 Do you see that? 21 A. Yes. 22 Q. And you call her -- you call 23 her analysis -- you basically say that she's 24 applying a non -- uniform noncompensatory</p>
<p style="text-align: right;">Page 123</p> <p>1 A. I'm not an expert in that. I 2 would not have an opinion. 3 Q. Okay. And when you discuss 4 healthcare decision-making, for example in 5 paragraph 1 of your report that we just read 6 in your assignment, you're not discussing the 7 decisions of congress and the FDA regarding 8 structural aspects of our healthcare system, 9 are you? That healthcare decision-making 10 you're focused on here is related to 11 physicians' and consumers' choices, correct? 12 A. It's more specific. It's 13 related to how consumers, sometimes on their 14 own and sometimes in conjunction with their 15 physicians, would assess the worthiness or 16 value of a drug, and in this particular case 17 the recalled VCDs. 18 Q. Okay. Let's stick with my 19 question, which is, you're not critiquing or 20 in any way discussing in your discussion of 21 healthcare decision-making the structural 22 aspects of our healthcare system that 23 congress and the FDA have set up, are you? 24 MR. GOLDBERG: Objection to</p>	<p style="text-align: right;">Page 125</p> <p>1 decision rule, do you not? 2 A. I do not say that. 3 Q. Take a look at paragraph 9 of 4 your report, first bullet point. You say in 5 the middle of that bullet point, "In doing 6 so, Dr. Conti's analysis implicitly relies on 7 a uniform noncompensatory decision-rule for 8 calculating damages." 9 Do you see that? 10 A. Yes. 11 Q. So you are saying that she's 12 applying a uniform noncompensatory decision 13 rule, do you not? 14 A. You forgot a critical word. 15 No, I did not say that, I said she is 16 implicitly applying. 17 Q. How is that different from her 18 applying, which is my question? 19 A. The different between an 20 explicit and an implicit application. She 21 does not mention a noncompensatory decision 22 rule, but her assertions are consistent with 23 a noncompensatory decision rule, which is why 24 I said she implicitly applies a</p>

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1 noncompensatory decision rule.
 2 Q. Okay. Thank you for that.
 3 That was going to be my next question, is
 4 Dr. Conti never uses that term in her report,
 5 does she?
 6 A. No.
 7 Q. Thank you.
 8 That's a term -- compensatory
 9 decision rules, noncompensatory decision
 10 rules, those are terms that are borne out of
 11 the field of sort of behavioral science,
 12 right? Consumer behavior, consumer
 13 psychology, your field of expertise, correct?
 14 A. As I mentioned in my testimony
 15 earlier, the foundation for some of this work
 16 on compensatory/noncompensatory decision
 17 rules came from economists, and I mentioned
 18 several, Simon, Tversky, Kahneman, amongst
 19 others.
 20 Simon actually was the first
 21 one that came up, from what I know, or is at
 22 least given credit for the first
 23 noncompensatory rule satisfying. This is
 24 Herbert Simon, he's an economist.

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1 Q. This is behavioral economics,
 2 correct?
 3 A. At that time it was not defined
 4 as such, but he's an economist, and now it is
 5 commonly adopted in behavioral economics as
 6 well.
 7 Q. Let's go to paragraphs 21
 8 through 28 of your report. And this is where
 9 you set forth some discussion and definitions
 10 of what you mean by compensatory decision
 11 rules and noncompensatory decision rules, is
 12 that correct?
 13 A. Yes.
 14 Q. For example, in paragraph 22
 15 you state that "The compensatory
 16 decision-rule involves physicians and
 17 consumers placing a higher value of one drug
 18 feature to compensate for a lesser value of
 19 another feature," correct?
 20 A. Yes.
 21 Q. There's an assumption there, is
 22 there not, that the information regarding
 23 those features is available for them to
 24 actually weigh, correct?

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1 A. No.
 2 Q. Explain to me how that could
 3 not be.
 4 A. Some consumers use their
 5 experiences to make judgments about which
 6 features are important, what weights they
 7 want to put on those features, and how they
 8 would evaluate those features even if they
 9 did not have any external information.
 10 Q. So what you're saying is that
 11 even if -- the consumers may make, you know,
 12 make -- draw conclusions without the
 13 information, correct?
 14 A. Yes.
 15 Q. Okay. But to actually weigh
 16 the benefits, the costs and benefits of a
 17 particular feature, that feature has to be
 18 disclosed to them, does it not?
 19 A. Explain what you mean by
 20 "disclosed."
 21 Q. How can someone weigh the costs
 22 and benefits of a particular feature of a
 23 medicine, for example, if the feature itself
 24 is not known to them?

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1 A. Well, I think you're making an
 2 assumption that the feature is not known to
 3 them unless someone else gives them the
 4 information.
 5 If they have no information on
 6 the feature regardless of the source, I agree
 7 with you, then they would probably not
 8 include it in their decision-making and their
 9 valuation. But they can get information from
 10 a variety of sources and decide which source
 11 they want to include, which source they don't
 12 want to include, and make the deliberation
 13 accordingly.
 14 Q. There's also an assumption here
 15 in this paragraph 22 that the drug, like the
 16 hypothetical drug you discuss here, you say,
 17 "placing a higher value of one drug feature
 18 to compensate for a lesser value of another
 19 feature," right? So you're discussing this
 20 in the context of a pharmaceutical drug
 21 product, correct?
 22 A. I don't believe a chewable
 23 multivitamin is a pharmaceutical drug
 24 product, but maybe it is.

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1 Q. Well, I'm not asking about
 2 chewable multivitamins. I'm asking about the
 3 first sentence of paragraph 22, "The
 4 compensatory decision-rule involves
 5 physicians and consumers placing a higher
 6 value of one drug feature to compensate for a
 7 lesser value of another feature."
 8 Do you see that?
 9 A. Yes.
 10 Q. Okay. And by "drug" there you
 11 mean a prescription drug, because you're
 12 saying physicians as well as consumers,
 13 correct?
 14 A. That is incorrect.
 15 Q. Okay. Well, it could
 16 include -- when you say "drug," what do you
 17 mean there?
 18 A. It could mean any kind of drug,
 19 over-the-counter, prescription, any kind of
 20 drug.
 21 Q. Okay. So that term "drug" does
 22 include prescription drugs?
 23 A. Yes.
 24 Q. Okay. Thank you.

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1 There's an assumption in there
 2 that that drug is actually available to them,
 3 correct, for them to be able to engage in
 4 some kind of meaningful compensatory decision
 5 rule, correct?
 6 A. Incorrect.
 7 Q. How could that be?
 8 A. As a consumer, I could think
 9 about, even if I -- something was available
 10 but not accessible to me, or not available
 11 because it was in short supply, or for some
 12 other reason, I could think about what the
 13 drug would -- how much value I would place on
 14 the drug if it were available, for example.
 15 Q. Okay. But you're not going to
 16 end up paying anything for it, correct,
 17 because it's not available regardless of what
 18 the outcome of the decision is, right?
 19 A. I mean, if there's no product
 20 or service, in this case a drug to pay for,
 21 I'm not going to pay for nothing.
 22 Q. Right. Exactly.
 23 A. Yes.
 24 Q. Let's take -- are you familiar

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1 with the drug Fen-Phen? Do you remember
 2 Fen-Phen?
 3 A. It sounds familiar, but I don't
 4 remember any details.
 5 Q. Okay. Fen-Phen was a weight
 6 loss drug that was widely used, and then
 7 pulled from the market in the late '90s due
 8 to severe side effects, so it's not available
 9 today.
 10 Do you understand that?
 11 A. I'll take your word for it.
 12 Q. Okay. Can a physician in --
 13 let's say a consumer patient goes in to their
 14 doctor today and says, I want you to
 15 prescribe me Fen-Phen.
 16 Do you follow me?
 17 A. Yes.
 18 Q. And the drug has been withdrawn
 19 from the market, it's not available.
 20 Do you follow me there?
 21 A. Yes.
 22 Q. Okay. What would -- the result
 23 of that discussion, no matter how much the
 24 patient wanted Fen-Phen, is that the patient

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1 is not going to get Fen-Phen, right?
 2 A. I will say that the physician
 3 cannot prescribe Fen-Phen.
 4 Q. Right. And the patient will
 5 not be able to lawfully get Fen-Phen,
 6 correct?
 7 MR. GOLDBERG: Objection to
 8 form.
 9 A. I don't want to make any
 10 assumptions here. So, for example, they
 11 could go to another country and lawfully get
 12 Fen-Phen. I don't want to make an
 13 assumption.
 14 BY MR. DAVIS:
 15 Q. Okay. I'm talking --
 16 everything we're talking about today, I'm
 17 talking about in the US.
 18 A. Okay.
 19 Q. In the US, a patient really
 20 wants Fen-Phen, they go in to their doctor
 21 and ask for it, they're not going to be able
 22 to get it here because of the way our
 23 prescription drug system works, right? You
 24 need a prescription from a doctor to get

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1 Fen-Phen, and it needs to be available,
 2 approved, and able to be marketed, correct?
 3 A. If Fen-Phen was a prescription
 4 drug, yes.
 5 Q. So whatever the decision
 6 analysis that the consumer, you know, arrived
 7 at based on what they wanted out of Fen-Phen,
 8 the serious side effects that ultimately made
 9 it unavailable, the outcome of that is going
 10 to be they're not going to get Fen-Phen in
 11 the US, correct?
 12 A. In your hypothetical example,
 13 yes.
 14 Q. Right.
 15 And therefore, they're not
 16 going to pay anything for Fen-Phen, correct?
 17 A. Again, there's an assumption
 18 there. There are some consumers who would
 19 have had to pay nothing even if Fen-Phen was
 20 available, so yes.
 21 Q. Okay. Right. They're not
 22 going to pay for it, correct?
 23 A. Right. I'm just clarifying
 24 that they may not have had to pay for it even

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1 if it were available in some circumstances.
 2 Q. I'll grant you that.
 3 But the outcome is going to be
 4 they're not going to pay for it, right?
 5 A. Correct.
 6 Q. You mentioned your multivitamin
 7 example, I believe that's in
 8 paragraph twenty -- yeah, paragraph 22,
 9 sorry, just on the next page, and then
 10 spilling over into paragraph 23, right?
 11 A. Right.
 12 Q. Do you know whether
 13 multivitamins are subject to the same
 14 approval framework as prescription drugs?
 15 A. No.
 16 Q. Okay. Do you know whether any
 17 generic multivitamin must demonstrate that
 18 it's somehow equivalent to some brand
 19 multivitamin in order to be marketed?
 20 A. No.
 21 Q. Another example you provide is
 22 Accutane.
 23 Do you recall that?
 24 A. Yes.

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1 Q. Okay. And that appears around
 2 paragraphs 38 and 39 of your report, right?
 3 A. Right.
 4 Q. Okay. What's the point you're
 5 trying to make with this Accutane example
 6 here?
 7 A. The general point I'm trying to
 8 make is as a consumer behavior expert, I want
 9 to emphasize that consumers have agency, and
 10 that they can and do make choices even when
 11 they may know about negative side effects to
 12 others and even to themselves.
 13 Q. Okay. Those side effects you
 14 mention, those are all inherent to the drug
 15 itself, correct?
 16 MR. GOLDBERG: Objection to
 17 form. Vague and ambiguous.
 18 A. I don't understand.
 19 BY MR. DAVIS:
 20 Q. Sure.
 21 Is there some version of
 22 Accutane out there that you're aware of that
 23 does not carry those side effects?
 24 A. I cannot speak to that.

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1 Q. You haven't investigated that
 2 one way or the other?
 3 A. No.
 4 Q. Can't you deduce that if a
 5 generic drug like we've talked about has to
 6 show that it's the same as the brand drug in
 7 a lot of ways, can't you deduce that Accutane
 8 and its generic equivalents out there would
 9 all carry the same risk of these various side
 10 effects?
 11 A. No.
 12 Q. You can't deduce that?
 13 A. No.
 14 Q. Okay. Do you know whether the
 15 FDA label -- have you looked at the FDA label
 16 for Accutane?
 17 A. No.
 18 Q. Okay. That's -- do you
 19 understand that the FDA label would be
 20 exactly where those side effects are
 21 disclosed regarding Accutane?
 22 A. I'm not an expert. I'll take
 23 your word for it.
 24 Q. Okay. And do you have any

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1 understanding of whether the generic label
 2 for generic Accutane has to read exactly the
 3 same way with regard to those side effects as
 4 brand Accutane's label?
 5 A. Not an expert. I'll take your
 6 word for it.
 7 Q. And you don't understand why
 8 the FDA requires that that label be read the
 9 same way, do you?
 10 A. Not an expert on the FDA
 11 processes. I'm not going to form an opinion.
 12 MR. DAVIS: I'm handing
 13 Exhibit 5 to be marked.
 14 (Whereupon, Keller Exhibit
 15 Number 5 was marked for
 16 identification.)
 17 BY MR. DAVIS:
 18 Q. I'm not going to burden you
 19 with reading the entire Accutane label here.
 20 Did you -- I guess just answer me this.
 21 Did you, in coming up with your
 22 Accutane example in your report, did you look
 23 at the label for the drug? I think you said
 24 no, right?

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1 A. No.
 2 MR. GOLDBERG: Objection.
 3 Asked and answered.
 4 BY MR. DAVIS:
 5 Q. In your report on paragraph 38
 6 you mention that Accutane "has a number of
 7 potentially serious side effects, including:
 8 eye irritation; skin infection; bone
 9 tenderness; vision loss; birth defects (in
 10 pregnant women); skin inflammation."
 11 Do you see that?
 12 A. Yes.
 13 Q. Where did you get that
 14 information from?
 15 A. Footnote 62, and it's in
 16 Appendix B of my report.
 17 Q. Okay. So that is -- that
 18 appears to be the label, so you did --
 19 A. I didn't know that's what the
 20 label was. Thank you.
 21 Q. Yes. So this is the label. So
 22 you have looked at this?
 23 A. Yes.
 24 Q. And that's how you pulled out

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1 for example, these potential side effects,
 2 was from looking at what's been marked as
 3 Exhibit 5, correct?
 4 A. Sorry, can you repeat the
 5 question? What has been -- sorry, can you
 6 ask the question again?
 7 Q. Sure.
 8 The way you came to understand
 9 that Accutane carries the risk of these side
 10 effects that you discuss in paragraph 38 is
 11 because, as you cite in footnote 62, you
 12 actually went and looked at the label for the
 13 drug, correct?
 14 A. That's right.
 15 Q. Okay. And that's where those
 16 side effects were disclosed?
 17 A. I'm sure -- there may be more,
 18 but that's where the ones I've listed were
 19 disclosed, yes.
 20 Q. So essentially what happened
 21 here is the FDA approved Accutane, correct?
 22 The FDA granted approval for Accutane to be
 23 marketed to Roche, which was the brand
 24 company as you see there.

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1 Do you understand that?
 2 A. I take your word for it.
 3 Q. And they approved Accutane
 4 despite the drug carrying these disclosed
 5 side effects, correct?
 6 A. I'll take your word for it.
 7 Q. And left it up to physicians
 8 and consumers to weigh the costs and benefits
 9 of taking the medicine with those -- with the
 10 knowledge of those disclosed side effects in
 11 the label, right?
 12 A. Yes.
 13 Q. Okay. Let me ask you, how do
 14 you think users of --
 15 A. Should I put this away?
 16 Q. Sure, if you want to.
 17 How do you think users of
 18 generic Accutane manufactured by Ranbaxy
 19 weighed the fact that that generic Accutane
 20 was contaminated?
 21 A. Could you please repeat the
 22 question?
 23 Q. Sure.
 24 Are you familiar with a company

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1 called Ranbaxy?
2 A. No.
3 Q. Okay. Let me mark something
4 else for you.
5 MR. DAVIS: I'm handing
6 Exhibit 6 to the reporter to be
7 marked.
8 (Whereupon, Keller Exhibit
9 Number 6 was marked for
10 identification.)
11 BY MR. DAVIS:
12 Q. Okay. I'm handing you a --
13 Exhibit 6, for the record, is a US Department
14 of Justice press release titled "Generic Drug
15 Manufacturer Ranbaxy Pleads Guilty and Agrees
16 to Pay \$500 Million to Resolve False Claims
17 Allegations, cGMP Violations and False
18 Statements to the FDA."
19 Do you see that?
20 A. I see it.
21 Q. That's dated May 13, 2013?
22 A. I see.
23 Q. Okay. So, in fact, if you --
24 just to orient you, if you go back to

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1 Exhibit 5 just for a moment, which is the
2 Roche label for Accutane, do you see what the
3 generic name for that drug is?
4 A. Exhibit -- where? It's a big
5 document.
6 Q. Well, actually it's in your
7 report at paragraph 38, "As an example,
8 Accutane, or isotretinoin."
9 A. Yes.
10 Q. Do you know that Accutane's
11 generic name is isotretinoin?
12 A. Yes.
13 Q. Okay. I'm going to direct your
14 attention to page 2 of Exhibit 6, which is
15 this DOJ announcement.
16 A. Okay.
17 Q. And you'll see in the second
18 paragraph on that page, "Ranbaxy USA admitted
19 to introducing into interstate commerce
20 certain batches of adulterated drugs that
21 were produced at Paonta Sahib in 2005 and '6,
22 including Sotret, gabapentin, and
23 ciprofloxacin."
24 And then it says, "Sotret is

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1 Ranbaxy's branded generic form of
2 isotretinoin," which is Accutane, correct?
3 A. Is the generic form.
4 Q. Right.
5 A. Yes.
6 Q. So do you see there that
7 Ranbaxy admitted that in 2005 and '6 that
8 they distributed adulterated isotretinoin?
9 A. According to this statement,
10 yes.
11 Q. Okay. So my question is, how
12 do you think consumers of Ranbaxy's Sotret or
13 isotretinoin manufactured by them who got
14 that drug in 2005 and 2006 were able to weigh
15 at the moment they went to the pharmacy and
16 got it the fact that it was adulterated?
17 MR. GOLDBERG: Objection to
18 form.
19 I think it would be fair to
20 allow the witness to review the
21 document, given the question.
22 BY MR. DAVIS:
23 Q. You don't need to review the
24 document to answer the question. I'm asking

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1 you what I think is a pretty simple question.
2 How do you think consumers of
3 Ranbaxy's Sotret, which is, as we've seen,
4 generic Accutane, how do you think those
5 consumers in 2005 and '6 were able to weigh
6 the fact that it was adulterated when it was
7 dispensed to them at the time they purchased
8 the drug?
9 MR. GOLDBERG: I'm going to
10 place the same objection. I think the
11 witness can read the document, that
12 statement that you're asking her about
13 into context. You're sort of showing
14 her a document --
15 MR. DAVIS: This is
16 filibustering.
17 MR. GOLDBERG: It is not.
18 BY MR. DAVIS:
19 Q. Feel free, Dr. Keller, if you
20 want --
21 MR. GOLDBERG: You placed a
22 document in front of the witness, you
23 didn't give her a chance to review it.
24 Let her review the document, and let

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1 her answer the question.
2 BY MR. DAVIS:
3 Q. I'm not sure how helping the
4 document is going -- or reviewing the
5 document is going to help you answer the
6 question. I've set forth a fact that was
7 admitted to by Ranbaxy, which is that they
8 distributed in 2005 and 2006 certain
9 adulterated batches of isotretinoin.
10 You see that in the document,
11 do you not?
12 A. Yes.
13 Q. Okay. And you have no reason
14 to dispute what Ranbaxy is admitting there,
15 correct, that they did that?
16 A. Right.
17 Q. Okay. So my question to you
18 is, how do you think consumers who purchased
19 those adulterated isotretinoin prescriptions
20 in 2005 and 2006 were able to weigh the fact
21 that they were adulterated in 2005 and '6
22 when they actually bought the drugs?
23 A. This is the reason for wanting
24 to read the document, to see if there is any

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1 context that would help me answer the
2 question more accurately.
3 Q. The fact is they couldn't,
4 right? The answer is no, they can't weigh
5 that information, right, because they didn't
6 know it, right?
7 MR. GOLDBERG: Objection to
8 form.
9 A. Again, I don't know that. I
10 accepted what you said earlier when you
11 pointed to where I -- where that was in the
12 report. If you let me read this report, I'll
13 see if that same statement is made in the
14 report, and then you can ask me the question
15 again whether I have any reason to doubt it.
16 BY MR. DAVIS:
17 Q. Okay. Take a few moments.
18 MR. DAVIS: Let's go off the
19 record.
20 MR. GOLDBERG: No, let's not go
21 off the record. The document is a
22 couple of pages. Under the rules in
23 this case, the witness gets to read
24 the document for a few minutes, if

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1 it's going to take longer we'll go off
2 the record. But we don't go off the
3 record automatically just because a
4 document is presented. That's how it
5 goes.
6 BY MR. DAVIS:
7 Q. Feel free to give the document
8 a cursory review.
9 A. I'm sorry, I'm going to
10 undertake my task so that I can answer your
11 question to the best of my ability.
12 Q. Sure. Okay.
13 A. Thank you.
14 Q. Review the document.
15 A. Thank you.
16 (Witness reviewing document.)
17 A. Thank you.
18 Q. Sure. So let's start with the
19 portion of the document that I called out to
20 you.
21 You agree that Ranbaxy admitted
22 to distributing in 2005 and 2006 certain
23 batches of adulterated isotretinoin, which is
24 generic Accutane, correct?

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1 A. Yes.
2 Q. Okay. So my question is, how
3 can consumers who purchased those drugs in
4 2005 and '6 have weighed the fact that they
5 were adulterated at the time that they
6 purchased them?
7 A. You are making an assumption
8 that consumers uniformly would have wanted to
9 weigh that fact.
10 Q. No, that's not my question, and
11 you're not answering my question.
12 My question is, how could they
13 have weighed that information when it wasn't
14 disclosed to them?
15 A. But the assumption is that they
16 would even want to. So if I don't want to,
17 the issue of how I could is irrelevant.
18 Q. Well, you're taking it --
19 you're taking my question and you're
20 answering a different question.
21 A. I see.
22 Q. My question is, how can
23 consumers who purchased adulterated Ranbaxy
24 isotretinoin in 2005 and 2006 that was

<p style="text-align: right;">Page 150</p> <p>1 adulterated, how could they have weighed the 2 fact that it was adulterated? If they wanted 3 to weigh that fact, how could they have 4 weighed that fact that it was adulterated? 5 They couldn't, right? 6 A. Again, I'll explain why I'm 7 having a hard time answering that question 8 directly. 9 Based on my understanding of 10 consumer behavior, there are consumers who 11 think drugs are adulterated when they're not 12 and consider that. And the example that I 13 give in my report was on -- because we were 14 talking about COVID vaccine earlier, about 15 bleach, and I cited a supporting document, 16 you know, something from the CDC on the 17 percentage of people that were using bleach 18 because they thought that was more 19 efficacious for them or safer or whatever set 20 of reasons they had that I'm unsure of than 21 the COVID-19 vaccine. 22 So I don't -- I said this 23 earlier, I don't think that consumers need to 24 get specific information in order for them to</p>	<p style="text-align: right;">Page 152</p> <p>1 question. You're answering a different 2 question, which is how they might have 3 weighed that information or not have weighed 4 that information. 5 My question is, it wasn't 6 disclosed to them, so even if they wanted to 7 weigh it they couldn't have, right? Even if 8 they would have considered that in their 9 decision-making, they couldn't have, right, 10 because it wasn't disclosed to them. Would 11 you agree with that? 12 A. So you're saying make the 13 assumption that people -- that there were 14 people who wanted to know, and then -- you're 15 asking me to make a lot of assumptions. 16 Q. Well, I don't think it's a big 17 assumption to assume that people would want 18 to know that their drug was contaminated. 19 A. Some will and some will not, 20 and that's what I said. 21 Q. Assume it for me, Dr. Keller, 22 assume that there were patients of Ranbaxy's 23 Sotret who would have wanted to know that 24 information.</p>
<p style="text-align: right;">Page 151</p> <p>1 include features, whether they're benefits or 2 costs or both in some cases, in order to make 3 a determination of how they impact the value 4 that they are assessing. 5 Q. You don't think consumers are 6 entitled -- you don't think these Ranbaxy 7 isotretinoin consumers were entitled to know 8 that the drug they got was adulterated? Is 9 that what you're saying? 10 A. No, I did not say that. I 11 actually don't know what you mean by 12 "entitled." 13 Q. You don't think it would have 14 been right for them to know that the drug 15 they were getting was adulterated? 16 A. There are some consumers who 17 would say, It is my right to know, and there 18 are others who would say, I don't care. 19 There is a range of consumer 20 behavior, and I don't think that you can 21 uniformly assume any consumer would be 22 exactly the same in this context of they 23 would feel that they have the right to know. 24 Q. But you're not answering my</p>	<p style="text-align: right;">Page 153</p> <p>1 A. Okay. 2 Q. But they didn't know that 3 information at the time they purchased the 4 drug, right? 5 A. Correct. 6 Q. Okay. How could they have 7 weighed that information when it wasn't 8 disclosed to them? They couldn't have, 9 right? They could not have weighed that 10 information, correct? 11 A. They could not have weighed the 12 specific information, but they could have 13 weighed related information. 14 Q. What do you mean by "related 15 information"? 16 A. You know, there are consumers 17 out there who believe that pure drugs is an 18 oxymoron, and that -- you know, and as I 19 state in my report in Section IV, I think it 20 was IV.B, which is what we were referring to 21 earlier, there are some consumers who learn 22 over time that things that they thought were 23 safe were not safe, and things that they 24 thought may have not been safe have reentered</p>

<p style="text-align: right;">Page 154</p> <p>1 the market in a different form or in some 2 other form. 3 So I think the situation is 4 much more fluid, and that consumers are aware 5 of this. 6 Q. So you're saying that you don't 7 think consumers should be entitled to expect 8 that the drugs that are distributed to them 9 at the pharmacy are as approved by the FDA? 10 A. I would never use consumers, if 11 your -- I would never agree to any sentence 12 that says "consumers" if by that you mean all 13 consumers. 14 Q. I'm asking, because you said 15 that -- I think you said that the notion of a 16 pure drug was an oxymoron. Is that what you 17 said? 18 A. I said for some consumers, not 19 for -- remember, I'm doing -- I'm applying 20 the same rule to myself that I'm applying to 21 you. I said for some consumers. I would not 22 say for all consumer a pure drug is an 23 oxymoron. 24 Q. So what you're saying is you</p>	<p style="text-align: right;">Page 156</p> <p>1 know that so you could just take another 2 manufacturer's version of generic Accutane 3 that wasn't adulterated? 4 A. It's a hypothetical, so I'm 5 giving you a hypothetical back, and that is, 6 if I like this one that I'm taking and it's 7 worked for me -- and back to my framework 8 that I talk about in the model, and I'll use 9 MICI this time, which is, depending on the 10 message that I got -- and I can give you 11 examples, depending on -- I'm focusing on the 12 individual differences, that if I've tried 13 other acne medicines and they haven't worked 14 for me, and then I find one that I really 15 like and it seems to work for me, and then 16 there is this information out there, I'm 17 saying that there are some consumers in those 18 situations that might not want to know or not 19 care about this information about the 20 adulteration from this specific batch because 21 they don't want to switch, they don't want to 22 consider any alternative products. 23 Q. Do you understand that the 24 point of our generic drug system is that all</p>
<p style="text-align: right;">Page 155</p> <p>1 don't think consumers of pharmaceuticals 2 dispensed in the US should be entitled to a 3 belief or an expectation that those drugs are 4 dispensed to them as described and approved 5 by the FDA? 6 A. Again, I don't believe that is 7 the case for all consumers. I think many 8 consumers don't think about whether the drug 9 is approved or not approved, or who approves 10 it or doesn't approve it. 11 And I'm going to break one of 12 my own rules and give you an example where if 13 I was taking a drug, and it could be this one 14 that you have as an example, and I thought it 15 was working brilliantly for me, I might not 16 want to know that the drug -- I mean, sorry, 17 I can say drug, yeah -- that the drug was 18 adulterated because I would like to continue 19 taking the drug without any trepidation. 20 Q. You might not want to know? 21 A. I might not want to know. 22 Q. Well, what if -- I mean, we're 23 talking about just one manufacturer's version 24 of generic Accutane, you wouldn't want to</p>	<p style="text-align: right;">Page 157</p> <p>1 the generics are supposed to work in the same 2 way to each other and to the brand? 3 MR. GOLDBERG: Objection. 4 BY MR. DAVIS: 5 Q. Do you understand that? 6 MR. GOLDBERG: Objection to 7 form. Asked and answered. 8 A. I am not an expert on how 9 generics are supposed to work, and I will not 10 give you an opinion on that. 11 BY MR. DAVIS: 12 Q. Let's back up for a second. 13 You talk a lot about this 14 choice exercise that consumers make in the 15 healthcare context, right? 16 A. Which context are you speaking? 17 We were talking about how a consumer might 18 value the drug that they have, so when you 19 say "choice exercise," I'm trying to 20 understand the context. 21 Q. Sure. 22 Your whole report is about 23 healthcare decision-making, right? And that 24 involves a choice, right?</p>

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1 A. I would say that that's a bit
2 of a mischaracterization. The bulk of my
3 report is focused on how consumers would
4 assess the value or worth of a drug to them.
5 Q. Okay. And once they make that
6 assessment, at what point is the decision
7 finalized for them?
8 A. Lots of cases, never. In some
9 cases, they try one, they never switch. That
10 varies by consumer.
11 Q. Well, the choice is culminated
12 when they go buy the drug, right? They're
13 acting, would you agree --
14 A. No, no.
15 Q. Would you agree that a
16 consumer, when they go fill a prescription,
17 they're acting on a choice that they've made,
18 correct? They may -- I hear what you're
19 saying, they may reevaluate that choice in
20 the future, but they're acting on a choice
21 that they made prior to that, because they
22 had to -- I mean, it's just common sense, you
23 go fill a prescription, you're doing an act,
24 right?

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1 A. As I mentioned to you earlier,
2 the consumer value is defined as a comparison
3 of benefits and costs, and the price they pay
4 or the act of actually exchanging a product
5 for money is only one aspect of the cost.
6 Q. It's an action, though, that a
7 consumer is taking, correct?
8 A. It's one of several.
9 Q. As a result of the decision and
10 choice analysis that they went through prior
11 to engaging in that act, right?
12 A. I take objection to that. As I
13 explain in my report, and this is in Section
14 IV.B of my report, consumers use a variety of
15 different methods to make those choices.
16 Some of them are noncompensatory or
17 reflexive, they haven't thought about
18 anything, they've just gone and done it
19 spontaneous, others -- there's a range --
20 others will spend a lot of time and think
21 about the plusses and minuses. There's a
22 range.
23 Q. I'm not going into the
24 qualitative aspect of that choice. All I'm

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1 saying is that in order to act, which is to
2 go fill the prescription at the pharmacy,
3 some level of choice had to be made to go do
4 that. We're not talking about zombies here
5 who are just like, you know, going to the
6 pharmacy, this is a choice that humans make
7 to go fill a prescription, is it not?
8 A. I would say some will go fill
9 and some will not. And again, as is
10 explained in my report, many consumers do not
11 fill their prescriptions, and many consumers
12 who fill their prescriptions do not take
13 their drugs. So those are also actions.
14 Q. So with this Sotret example,
15 which consumers affirmatively made the choice
16 to go get adulterated Sotret from Ranbaxy?
17 A. I have no idea.
18 Q. None, right?
19 A. Well, no, that is -- I have no
20 information on that. I can't tell you that.
21 Q. If you don't know -- if they
22 didn't know about it, how could they
23 affirmatively go choose that at the time?
24 They can't, right?

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1 A. I'm going to repose -- I'm
2 going to, sorry, reframe, reframe that
3 question.
4 Compare that to a consumer who
5 should have had the information, could have
6 had the information but did not, right? What
7 is the difference between their action and
8 someone who could not have known?
9 Q. Do you have any -- is there any
10 indication in this DOJ announcement that you
11 read that any consumer had any indication, or
12 any ability to even go and find out that
13 Ranbaxy's Sotret was adulterated at the time
14 it was dispensed to them?
15 A. That information is not
16 contained in this document.
17 Q. In fact, the opposite is
18 contained in the document, right? Part of
19 the settlement was related to Ranbaxy knowing
20 and not telling the FDA until 2007, which is
21 years after the adulterated Sotret was
22 distributed in 2005 and '6, right? So the
23 indication in this document at least is that
24 no one knew except Ranbaxy, right?

<p style="text-align: right;">Page 162</p> <p>1 A. I don't know that to be a fact.</p> <p>2 Q. Okay. Take a look at the last</p> <p>3 paragraph of page 3 of this document. It</p> <p>4 says -- and this is a quote from John Roth,</p> <p>5 the director of the FDA's office of criminal</p> <p>6 investigations. He says, "The FDA expects</p> <p>7 that companies will comply with the cGMP</p> <p>8 requirements mandated bylaw so that consumers</p> <p>9 can be assured that their medical products</p> <p>10 are safe and pure."</p> <p>11 Do you see that?</p> <p>12 A. Yes.</p> <p>13 Q. Okay. Is there anything about</p> <p>14 that statement that you disagree with?</p> <p>15 A. I am not an expert on the FDA,</p> <p>16 so I have no idea what they expect companies</p> <p>17 to do.</p> <p>18 Q. Do you think that consumers are</p> <p>19 entitled to the same expectation that the FDA</p> <p>20 has here, which is that their medical</p> <p>21 products are safe and pure?</p> <p>22 A. Again, it depends on how you</p> <p>23 ask consumers those questions. If they had</p> <p>24 to make trade-offs, they might make different</p>	<p style="text-align: right;">Page 164</p> <p>1 that are substandard, ineffective, or</p> <p>2 unsafe."</p> <p>3 Do you see that?</p> <p>4 A. Yes.</p> <p>5 Q. Okay. Do you agree from a --</p> <p>6 put your marketing consumer-patient messaging</p> <p>7 hat on -- do you agree that that would</p> <p>8 complicate your job if the integrity of the</p> <p>9 FDA's approval process was undermined?</p> <p>10 A. I cannot answer that question.</p> <p>11 Q. Okay. You don't think it would</p> <p>12 be harder, for example, to advocate for</p> <p>13 medication compliance when -- if the approval</p> <p>14 process for that very medication was -- the</p> <p>15 integrity of it was undermined because</p> <p>16 companies were selling adulterated drugs?</p> <p>17 MR. GOLDBERG: Objection to</p> <p>18 form. Ambiguous.</p> <p>19 A. I cannot answer that question.</p> <p>20 BY MR. DAVIS:</p> <p>21 Q. On page 3, back to page 3 of</p> <p>22 Exhibit 6, you'll see a paragraph, second to</p> <p>23 last paragraph, "Last year" -- which would</p> <p>24 have been 2012 based on the date of this</p>
<p style="text-align: right;">Page 163</p> <p>1 trade-offs on how important safety or purity</p> <p>2 might be to them if it meant lower efficacy</p> <p>3 or lower experience for them.</p> <p>4 Q. So you're saying that consumers</p> <p>5 of prescription drugs in the US should be</p> <p>6 forced into a position of making a trade-off</p> <p>7 that includes whether their products are safe</p> <p>8 or pure?</p> <p>9 A. That is not what I said.</p> <p>10 Q. Wouldn't that position</p> <p>11 completely undermine our prescription drug</p> <p>12 approval framework in this country?</p> <p>13 A. I am not an expert on the</p> <p>14 approval drug process, and I am not offering</p> <p>15 an opinion on it.</p> <p>16 Q. Okay. Go back to page 1 of</p> <p>17 this document, which is Exhibit 6 for the</p> <p>18 record. Another quote from Stuart Delery,</p> <p>19 who was acting assistant attorney general for</p> <p>20 the civil division of the department -- U.S.</p> <p>21 Department of Justice. He says, "When</p> <p>22 companies sell adulterated drugs, they</p> <p>23 undermine the integrity of the FDA's approval</p> <p>24 process and may cause patients to take drugs</p>	<p style="text-align: right;">Page 165</p> <p>1 document -- "FDA and Ranbaxy agreed to an</p> <p>2 injunction that prevents drugs produced at</p> <p>3 the Paonta Sahib and Dewas facilities from</p> <p>4 entering the US market until the facilities</p> <p>5 have been brought into full compliance with</p> <p>6 the FDCA and its implementing regulations."</p> <p>7 Do you see that?</p> <p>8 A. Yes.</p> <p>9 Q. So for that period of time from</p> <p>10 the beginning of the injunction until a</p> <p>11 determination of full compliance was made,</p> <p>12 there was no consumer in the US market who</p> <p>13 could have gotten a Ranbaxy drug produced at</p> <p>14 those two facilities, right? Is that what</p> <p>15 that says?</p> <p>16 A. I will make that assumption</p> <p>17 that there were no leftovers or -- there's</p> <p>18 many assumptions there, but okay.</p> <p>19 Q. And so, therefore, there would</p> <p>20 have been no supply of drugs from those</p> <p>21 facilities, correct, entering the US market?</p> <p>22 MR. GOLDBERG: Objection to</p> <p>23 form.</p> <p>24 A. Please explain that.</p>

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1 BY MR. DAVIS:
2 Q. I'm not sure what there is to
3 explain.
4 There would have been no supply
5 of drugs from those two facilities that could
6 have entered the US market for the period of
7 the injunction, correct?
8 MR. GOLDBERG: Objection to
9 form. Foundation.
10 A. So can you please explain what
11 period we're talking about?
12 BY MR. DAVIS:
13 Q. Sure.
14 The period that I thought we
15 had understood, which was the beginning of
16 the injunction until full compliance.
17 A. So I'm not a lawyer, and, you
18 know, I need to understand. You know, these
19 are fluent terms for you.
20 So when you say "the beginning
21 of the injunction," what -- and you're asking
22 me about a time period, so what time period
23 am I referring to?
24 Q. The date of the injunction last

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1 year, so 2012, FDA and Ranbaxy agreed to an
2 injunction.
3 A. So from 2012 to?
4 Q. Whatever that date was that
5 they were brought into full compliance, if
6 that date ever occurred, would you agree with
7 me that there was no supply of Ranbaxy drugs
8 from those two facilities that could have
9 entered the US market?
10 A. I am not an expert on this and
11 I cannot answer that question.
12 Q. I mean, it just plainly says it
13 there, doesn't it?
14 MR. GOLDBERG: Objection to
15 form. Argumentative.
16 A. It's not plain to me.
17 BY MR. DAVIS:
18 Q. So the FDA and Ranbaxy agreeing
19 to an injunction that, quote, prevents drugs
20 produced at the two facilities from entering
21 the US market, that doesn't suggest to you
22 that, for that time period, that there was no
23 supply of Ranbaxy drugs into the US market
24 from those two facilities?

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1 A. I will repeat why I am not
2 saying that there was no supply. In part, I
3 don't know what supply there already was in
4 the marketplace, I don't know what -- how it
5 was recalled, I don't know what instructions
6 people gave, physicians and otherwise, as to
7 what people should do with whatever supply
8 was available, and I actually from this
9 sentence don't even know.
10 It says earlier that they're
11 going to work with them. I don't know when
12 they started working with them and allowed
13 them to reenter the market. I don't know.
14 Q. Do you know what happens to the
15 supply of pharmaceuticals that are already in
16 the market once a recall is announced? Do
17 you know what happens to those pills that are
18 sitting on warehouse shelves or pharmacy
19 shelves after the recall is announced?
20 A. I am not an expert on this, and
21 I will not form an opinion.
22 MR. GOLDBERG: John, I think
23 we've been going about 90 minutes.
24 MR. DAVIS: Sure. Five

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1 minutes?
2 We can go off the record.
3 MR. GOLDBERG: Yes, let's go
4 off the record.
5 THE VIDEOGRAPHER: Off the
6 record at 1:53.
7 (Whereupon, a recess was
8 taken.)
9 THE VIDEOGRAPHER: Back on the
10 record at 2:09.
11 BY MR. DAVIS:
12 Q. Okay. Dr. Keller, we left off,
13 I was asking you about this FDA Ranbaxy
14 injunction, I was asking you how that would
15 have affected the supply of Ranbaxy's in this
16 case Sotret that we were talking about into
17 the market that was produced at these two
18 facilities, into the US market.
19 Do you recall that discussion?
20 A. I recall the discussion before
21 the break, yes.
22 Q. Okay.
23 A. Should I bring this document
24 forth again?

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1 Q. No, I was resetting our --
2 A. I'm sorry. Okay.
3 Q. -- context here.
4 Have you examined in any detail
5 how the fact of adulteration in this case,
6 for example, affects a company's ability to
7 supply their drugs into the US?
8 A. I need a clarification.
9 Q. Sure.
10 A. In this case are we talking
11 about the Ranbaxy case, or are we talking
12 about the VCD case, or some other case?
13 Q. I'm just talking generally
14 about pharmaceutical prescription drugs.
15 A. Okay.
16 Q. Did you as part of this
17 assignment, or not as part of this
18 assignment, just generally, have you ever
19 studied how the fact of a prescription drug's
20 adulteration affects its ability to be
21 distributed, marketed, sold, dispensed in the
22 United States?
23 MR. GOLDBERG: Objection.
24 Ambiguous and compound.

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1 A. I am not an expert on many of
2 the things that were raised, and I'm not
3 going to give an opinion.
4 BY MR. DAVIS:
5 Q. So you haven't looked into how
6 the fact of adulteration might affect the
7 supply of a drug in the US?
8 A. Not prior to this case.
9 Q. Did you in this case?
10 A. I reviewed Dr. Conti's report,
11 so yes.
12 Q. Okay. I'm asking not did you
13 review Dr. Conti's report. I'm asking if you
14 did any independent analysis of your own how
15 the fact of adulteration under the law might
16 affect the supply or the ability of a
17 manufacturer to supply its drug product in
18 the United States market?
19 A. No. I am a consumer behavior
20 expert. I have no opinion on drug supply for
21 the example you've given.
22 MR. DAVIS: I'm going to mark
23 Exhibit 7.
24 ///

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1 (Whereupon, Keller Exhibit
2 Number 7 was marked for
3 identification.)
4 BY MR. DAVIS:
5 Q. I understand you're not a
6 lawyer, Dr. Keller. What I'm showing --
7 MS. ANDRAS: Can you please
8 identify it with specificity on the
9 record?
10 MR. DAVIS: Sure. For the
11 record, this is Exhibit 7, which is 21
12 USC 331, part of the US Code entitled
13 "Prohibited Acts."
14 BY MR. DAVIS:
15 Q. Do you see that?
16 A. Yes.
17 Q. Do you have familiarity with
18 what the US Code is?
19 A. No.
20 Q. Do you understand that that's
21 federal law enacted by congress, signed by
22 the President?
23 MR. GOLDBERG: Objection to
24 form. Foundation.

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1 A. I did not know that. I'm not
2 an expert on the law.
3 BY MR. DAVIS:
4 Q. Okay. I'm granting you that.
5 It says there that, "The
6 following acts and the causing thereof are
7 prohibited." And then it says, "(a) The
8 introduction or delivery" into -- sorry.
9 "The introduction or delivery for
10 introduction into interstate commerce of
11 any," and it lists several things, including
12 drugs, that are adulterated or misbranded.
13 Do you see that?
14 A. Yes.
15 Q. Okay. And then (c) says, "The
16 receipt in interstate commerce of any" of the
17 same categories, including drugs, that are
18 adulterated or misbranded, and the delivery
19 or preferred delivery thereof for pay or
20 otherwise.
21 Do you see that?
22 A. I do.
23 Q. Okay. Were you aware -- your
24 testimony is you're not aware of these

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1 prohibitions under federal law, are you?
2 A. Correct.
3 Q. Okay. Thank you.
4 MR. GOLDBERG: Are you done
5 with this one?
6 MR. DAVIS: For the moment,
7 yes.
8 BY MR. DAVIS:
9 Q. Do you have any opinion about,
10 or -- let me rephrase it.
11 Do you have any understanding
12 about whether the at-issue VCDs in this case
13 were deemed to be adulterated or misbranded
14 under the law?
15 A. I don't have an opinion.
16 Q. Okay. You don't have any
17 understanding, correct?
18 A. That's not what you asked. You
19 asked if I had an opinion. So could you
20 reask the question?
21 Q. Sure.
22 MR. HONIK: I'd like Maureen to
23 read it exactly as John posed.
24 THE WITNESS: Thank you.

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1 (Whereupon, the reporter read
2 back the question:
3 QUESTION: Do you have any
4 understanding about whether the
5 at-issue VCDs in this case were deemed
6 to be adulterated or misbranded under
7 the law?)
8 MR. HONIK: Not opinion.
9 A. I apologize.
10 Could you read that again?
11 (Whereupon, the reporter read
12 back the question:
13 QUESTION: Do you have any
14 understanding about whether the
15 at-issue VCDs in this case were deemed
16 to be adulterated or misbranded under
17 the law?)
18 A. I am not a lawyer. I do not --
19 I am not going to offer any opinion on that.
20 BY MR. DAVIS:
21 Q. Okay. And the question was,
22 you don't have any understanding of whether
23 they were or not, correct?
24 A. Please explain what you mean by

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1 "understanding."
2 Q. So my question was, do you have
3 any understanding of whether the at-issue
4 VCDs in this case were deemed to be
5 adulterated or misbranded under the law?
6 A. I will answer to the best of my
7 ability. I have read the -- as you can see
8 in Appendix B of my report, I have read a
9 couple of legal documents that explain that
10 some of the at-issue VCDs were found to be
11 adulterated and unbranded under the law.
12 Q. Okay. But you're not sure how
13 many, right? You said "some." You're not
14 sure whether it's some or all of them, are
15 you?
16 A. I am -- my understanding, which
17 is what you asked, is that of the VCDs that
18 were voluntarily recalled by the
19 manufacturers, some of them, not all of them,
20 were adulterated or unbranded.
21 Q. You're not sure how many that
22 is, though?
23 A. No.
24 Q. Okay. And you didn't do any

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1 independent analysis of whether that's true
2 or not true, right?
3 A. Correct.
4 Q. Okay. Do you have any
5 understanding of whether there are
6 valsartan-containing drugs out there that
7 don't have and never had NDMA and NDEA in
8 them?
9 A. I am not an expert. I will
10 qualify that some of the material that I have
11 in my supporting documents suggested --
12 indicated to me that there were levels of
13 these two impurities that you just mentioned,
14 but I am assuming they were acceptable
15 levels.
16 Q. So my -- that's not my
17 question, though. My question -- and I'll
18 reask it just to make sure we're clear, my
19 question is, do you have any understanding of
20 whether there were not at-issue VCDs
21 manufactured by entities other than the
22 defendants in this case that did not have any
23 NDEA or NDMA in them?
24 A. I have no information on them.

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1 Q. You have no information on
2 that.
3 Didn't look at it?
4 A. No.
5 Q. Didn't investigate it?
6 A. No. Not part of my task.
7 Q. Do you have any understanding
8 of whether NDMA or NDEA are supposed to be in
9 valsartan drugs?
10 A. I'm not an expert on the
11 formulation of these drugs. I have no
12 opinion.
13 Q. Okay. So you don't know
14 whether these two substances are supposed to
15 or not supposed to be in valsartan drugs?
16 A. I am not an expert. I cannot
17 comment as to the presence, absence, or
18 extent to which these are or are not
19 necessary for these drugs.
20 Q. Well, the drugs were recalled,
21 as you said, right?
22 A. (Nodding in the affirmative).
23 Q. Doesn't that indicate to you
24 that they weren't supposed to be in there?

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1 A. My caveat is when you say
2 they're not supposed to be there, my
3 understanding is that they are there, it's
4 just not they're not supposed to be there
5 above certain levels, and that's what I'm
6 qualifying.
7 Q. But you don't know whether
8 they're supposed to be there at all or not,
9 correct?
10 MR. GOLDBERG: Objection to
11 form. Foundation.
12 A. No.
13 BY MR. DAVIS:
14 Q. Did you look at a valsartan
15 label like you looked at the Accutane label?
16 A. I already testified that I
17 looked at valsartan product labels.
18 Q. Can you point me -- it may be
19 in there, I just want you to point me to
20 where in your materials considered that would
21 be.
22 A. I can show you from my report,
23 but I don't have the binder of all the -- and
24 actually there's maybe six on a page, they're

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1 visuals, in case you have those materials and
2 you're trying to look for them, but I can
3 help.
4 (Witness reviewing document.)
5 A. I'm -- I wish I had my
6 materials in front of me, but I'm going to --
7 I don't want to guess. It could be in the
8 drugs.com or the MedlinePlus. I'm picturing
9 the page in front of me, and they're pictures
10 of multiple labels with on the left side the
11 name, and on the right side the drug
12 manufacturer and the place of manufacture.
13 That's what I'm picturing.
14 Q. Okay. You say -- flip to
15 page 30 of your report, if you don't mind,
16 Exhibit 1.
17 A. Of course.
18 Q. The title of that section is
19 "Real-world Evidence Indicates that the
20 At-Issue VCDs Held Value," correct?
21 A. Yes.
22 Q. Okay. Did you look at any
23 sales data of -- sorry.
24 Did you look at any sales data

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1 of the actual sales of these drugs after the
2 recalls were announced?
3 A. Only information that was part
4 of Dr. Conti's report, not otherwise.
5 Q. So do you know what happened to
6 sales of these products after the recalls?
7 A. I don't recall.
8 Q. Sorry, give me a few moments
9 here. I should have two copies of all this
10 somewhere, but I don't. I'm just going to
11 mark one, it's big enough for, I think, you
12 to see it.
13 MR. DAVIS: This is being
14 marked as Exhibit 8, let's start with
15 that.
16 (Whereupon, Keller Exhibit
17 Number 8 was marked for
18 identification.)
19 BY MR. DAVIS:
20 Q. Let me represent to you that
21 what I'm showing you there is the monthly
22 prescription data for --
23 A. Should I put the -- my report
24 away?

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1 Q. Sure, sure.
 2 A. Thank you. Okay.
 3 Q. What I'm representing to you
 4 here is that what's marked as Exhibit 8 is a
 5 graph showing monthly prescription data for
 6 ZHP manufactured valsartan products.
 7 Do you understand what I mean
 8 by that?
 9 A. Yes.
 10 Can I ask a clarifying
 11 question --
 12 Q. Sure.
 13 A. -- so I know how to interpret
 14 this graph?
 15 Q. Yes.
 16 A. I see that the X axis is
 17 labeled as time, but the Y axis is not
 18 labeled, and so I'm not quite sure how to
 19 interpret a graph with only one labeled axis.
 20 I could be missing something.
 21 Q. Read for me, if you don't mind,
 22 the header up at the top there.
 23 A. "Monthly ZHP Rx's by Valsartan
 24 Product."

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1 Q. Okay. So what I'll represent
 2 to you that the Y axis is there is Rx's, which
 3 is prescriptions.
 4 Do you understand that?
 5 A. So these are prescription --
 6 just clarifying, these are prescriptions of
 7 valsartan over this period of time.
 8 Q. Correct, manufactured by ZHP.
 9 A. Right. Prescriptions that were
 10 given, filled, or -- just again clarifying,
 11 because it isn't labeled.
 12 Q. Prescriptions that were filled.
 13 A. Thank you.
 14 Q. Yes. Absolutely.
 15 You didn't look -- I think your
 16 testimony was you didn't actually look at any
 17 of the sales data, did you?
 18 A. Not unless it was in
 19 Dr. Conti's appendices.
 20 Q. Do you see that the sales
 21 abruptly dropped to zero?
 22 A. So can I now assume in the Y
 23 axis that the bottom is the zero?
 24 Q. Yes, yes.

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1 A. Okay. Then yes.
 2 MR. GOLDBERG: Objection to
 3 form.
 4 BY MR. DAVIS:
 5 Q. Do you understand why for ZHP
 6 the monthly sales dropped to zero?
 7 A. I don't have that information.
 8 Q. Did you come to any
 9 understanding or investigate whether similar
 10 to Ranbaxy, ZHP was barred from importing
 11 prescription drug products to the US?
 12 A. I just want to make sure,
 13 exporting, that ZHP was barred from -- we
 14 barred them from imports of their product,
 15 right?
 16 Q. Yes. ZHP products were made
 17 illegal to sell in the US, correct?
 18 A. Yes.
 19 MR. GOLDBERG: Objection to
 20 form.
 21 BY MR. DAVIS:
 22 Q. And subject to seizure by
 23 federal agents if they were imported or
 24 attempted to be distributed?

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1 A. I am not an expert on this
 2 process. I cannot form an opinion.
 3 Q. Well, you sort of do form an
 4 opinion, though. If you look at paragraph 71
 5 of your report, you have a hypothetical
 6 supply-demand curve, do you not?
 7 A. Excuse me, I need to get there.
 8 Could you ask that question
 9 again?
 10 Q. Sure.
 11 You said you don't have an
 12 opinion one way or the other on whether ZHP
 13 was barred from importing or selling its
 14 products in the US. Am I right about that?
 15 A. I'm not sure, that may have
 16 been before your last question, I don't
 17 recall that as your last question, so I'm
 18 trying to be accurate.
 19 MR. DAVIS: Could you read that
 20 last question? Sorry.
 21 (Whereupon, the reporter read
 22 back the following:
 23 QUESTION: And subject to
 24 seizure by federal agents if they were

<p style="text-align: right;">Page 186</p> <p>1 imported or attempted to be 2 distributed? 3 THE WITNESS: I am not an 4 expert on this process. I cannot form 5 an opinion. 6 QUESTION: Well, you sort of do 7 form an opinion, though. If you look 8 at paragraph 71 of your report, you 9 have a hypothetical supply-demand 10 curve, do you not. 11 THE WITNESS: Excuse me, I need 12 to get there. 13 Could you ask that question 14 again? 15 QUESTION: Sure. 16 You said you don't have an 17 opinion one way or the other on 18 whether ZHP was barred from importing 19 or selling its products in the US. Am 20 I right about that?) 21 BY MR. DAVIS: 22 Q. So let me -- I'll withdraw the 23 last question. 24 You do at paragraph 71 on</p>	<p style="text-align: right;">Page 188</p> <p>1 And some consumers would say, I 2 don't want any of this product, it is not 3 worth anything to me, all the way to the 4 other end of the continuum where you have 5 some consumers who would say, I'm consuming 6 these impurities in multiple forms and it's 7 of no consequence to me, and everything in 8 between. 9 That's what these alternative 10 demand curves, or multiple demand curves are 11 meant to represent. 12 So when you ask the question, 13 you know, are they hypothetical demand 14 curves, yes, they are, as that they're not 15 based on data, nor is the supply curve, by 16 the way, based on data, they're just 17 representing how my frameworks and opinions 18 would translate into alternative demand 19 curves. 20 Q. Okay. And that was -- I think 21 you've answered my next question, which is, 22 this is not informed by any look at data, is 23 it? These are hypothetical scenarios you're 24 putting forward, right?</p>
<p style="text-align: right;">Page 187</p> <p>1 page 43, the next page over, supply a 2 hypothetical supply-demand curve, do you not? 3 A. Several. 4 Q. Well -- 5 A. Several demand curves, and 6 therefore -- 7 Q. You have several demand curves, 8 but you have one supply, correct? 9 A. Yes, so a combination would be 10 several supply-demand curves. 11 Q. Right. But with one supply 12 line, correct? 13 A. Yes. 14 Q. And this is hypothetical, 15 right? This is a hypothetical supply-demand 16 curve, is it not? 17 A. Well, it is a figure, and the 18 changes or the alternatives of the demand 19 curve that I'm sharing with you here reflect 20 my argument that consumers would have 21 different assessments of what the drug would 22 be -- what the at-issue VCD would be to them, 23 and based on the compensatory/noncompensatory 24 decision rules and MICI.</p>	<p style="text-align: right;">Page 189</p> <p>1 A. Yes. 2 Q. And in fact, your supply curve 3 is just inconsistent with the facts if you 4 accept, for example, the ZHP graph as 5 actually representing the sales situation, 6 correct? 7 A. It is incorrect, because the 8 example that I'm giving you in my report is 9 that one can retrospectively go to those 10 consumers -- because there was supply, they 11 were supplied the product. I mean, I'm not a 12 lawyer, but how do you have a recall if 13 there's -- no product was given? How do you 14 make, what, ZHP or any manufacturer say they 15 committed fraud because they sold something 16 if they didn't sell anything. So if there's 17 no supply, how is it possible if someone 18 sells something that there's no supply. 19 So I'm just saying that this to 20 me is not relevant -- sorry, your -- what 21 exhibit is this? 22 Q. This is Exhibit 8. 23 A. Sorry. Oh, I see that. 24 Exhibit 8 does not help inform</p>

<p style="text-align: right;">Page 190</p> <p>1 my figure on page 43, because they were 2 supplied. And I'm saying that if you went 3 back retrospectively and asked those 4 consumers, Hey, given what you know now about 5 the impurities and whichever way you want to 6 define it -- and that is going to make a 7 difference how you define it and how you 8 communicate it and who communicates it -- how 9 would you assess the value of the work of 10 this -- of the at-issue VCD that you took. 11 And all this is saying here in 12 my figure is that you will get a range of 13 responses. 14 Q. What literature do you have to 15 support what appears to be your proposition 16 that an economic damages analysis should be 17 based on a retrospective look as opposed to 18 measuring at the time of injury? 19 A. I am not a lawyer. I don't 20 have an opinion on that. 21 Q. Okay. And you're not offering 22 an economic damages analysis here, are you? 23 A. No. 24 Q. And you're not qualified to do</p>	<p style="text-align: right;">Page 192</p> <p>1 A. That is incorrect. 2 BY MR. DAVIS: 3 Q. How is that incorrect? 4 A. Because the information in this 5 case, and some of it is described in Section 6 IV.E of my report, that not only was there 7 evidence that consumers continued to take the 8 recalled valsartan based on depositions from 9 plaintiffs, but that -- and I've quoted some 10 of them, but that physicians, and I've also 11 quoted some of them, encouraged some of their 12 patients to continue taking the recalled 13 valsartan until they had other options. 14 That is my understanding of why 15 there had to be supply if that was -- if the 16 information I just shared is true. 17 Q. That's existing supply, right, 18 what had been distributed, dispensed to 19 patients prior to the recall, correct? 20 My question is, after the point 21 of recall, are you aware of any evidence of a 22 single prescription of ZHP valsartan being 23 dispensed to a patient after the point of 24 recall?</p>
<p style="text-align: right;">Page 191</p> <p>1 that, correct? 2 MR. GOLDBERG: Objection to 3 form. 4 A. It was not my task. I did not 5 do that. 6 BY MR. DAVIS: 7 Q. So -- and we'll get to the 8 retrospective aspect of this later. 9 A. Should I put it away? 10 Q. Sure. 11 But my question is, after the 12 point of recall, there was no supply of ZHP 13 valsartan in the US, was there? 14 MR. GOLDBERG: Objection to 15 form. Foundation. 16 A. No. According to this graph, 17 based on how you described it to me, no more 18 prescriptions were filled for this product 19 after this period on the X axis. 20 BY MR. DAVIS: 21 Q. Correct. That means there was 22 no more supply of it, correct, in the US 23 market? 24 MR. GOLDBERG: Same objection.</p>	<p style="text-align: right;">Page 193</p> <p>1 A. I don't have that information. 2 Q. Okay. So your supply curve 3 here that you supply is just inconsistent 4 with the facts, correct? 5 A. No. 6 MR. GOLDBERG: Objection to 7 form. Argumentative. 8 A. And I'm assuming now you're 9 referring to my report, because we have 10 multiple supply curves here. 11 BY MR. DAVIS: 12 Q. I'm talking about your 13 hypothetical supply curve, not what the 14 actual data show. 15 A. Got it. 16 So could you please repeat the 17 question? 18 Q. Your hypothetical supply curve 19 here is uninformed by the facts of this case, 20 is it not? 21 A. This figure is -- and you can 22 look at the context before and after, and I 23 will read it out to you because it's on the 24 same page, 72, "As shown in the figure above,</p>

<p style="text-align: right;">Page 194</p> <p>1 there existed some original supply and demand 2 curve (denoted by 'Demand0' and 'Supply'), 3 which resulted in an equilibrium price, P0, 4 and equilibrium quantity, Q*. Instead of 5 removing the supply curve, and assuming zero 6 demand, it is more appropriate to envision 7 how each consumer's demand would shift due to 8 knowledge of the presence (or potential 9 presence) of impurities." 10 Q. Let me ask you about that. 11 You say that there would be an 12 equilibrium price, you just read me that, 13 right? 14 A. That's one. There are multiple 15 equilibrium prices based on which demand 16 curve you're referring to. 17 Q. Let me ask you a very specific 18 question, which is, after the point of recall 19 for ZHP, since you have that data right in 20 front of you, after the point of recall there 21 would have been no supply -- there would have 22 been no equilibrium price because there was 23 no supply, right? 24 A. Yes and no.</p>	<p style="text-align: right;">Page 196</p> <p>1 A. The very fact that consumers 2 are going and asking their physician for 3 Fen-Phen -- I'm not making any assumptions 4 about all consumers here, you know that -- 5 and there's a possibility that they knew 6 about the recall, and I'm going to go one 7 step further and say given my knowledge of 8 consumer-physicians' interactions, they might 9 have even asked the physician why it was 10 recalled, they still wanted it. 11 So that gives you some sense of 12 how consumers will calculate what is valuable 13 to them or what is worth to them, even if in 14 your example the product is not available. 15 Q. So, but my question is 16 different. My question is, there is no 17 equilibrium price. Let's say there was some 18 crazy consumer who said, Yes, I want the 19 carcinogen-laced valsartan, and went in and 20 asked their physician for that, the physician 21 couldn't give them ZHP valsartan, could he? 22 MR. GOLDBERG: Objection to 23 form. Argumentative. 24 A. Well, first I want to say, and</p>
<p style="text-align: right;">Page 195</p> <p>1 Q. Okay. Well, how is it 2 different from what you -- do you recall our 3 discussion of Fen-Phen earlier? 4 A. Yes. 5 Q. And you agreed with me that 6 even if a patient wanted to get Fen-Phen they 7 couldn't get it, they couldn't pay for it, 8 right? How is it different after the point 9 of recall for ZHP valsartan? 10 A. Let's use your Fen-Phen 11 example. What I'm trying to communicate here 12 is how consumers make decisions about what a 13 product is worth to them, and price is one 14 manifestation or reflection of that. It is 15 not the only one. Let me just finish. 16 Your Fen-Phen example, you 17 brought it up again, the way -- from my 18 recall of how you described the situation is 19 it was recalled, and if a consumer of 20 Fen-Phen went to their physician and asked 21 for Fen-Phen, they could not write a 22 prescription for Fen-Phen. Am I right? Is 23 that a good -- 24 Q. Yes.</p>	<p style="text-align: right;">Page 197</p> <p>1 I'm relying on my frameworks, depending on 2 how that message was communicated, if you say 3 carcinogen-laced the way you said it versus a 4 valsartan that may contain impurities, the 5 individual's -- I'm using MICI factors -- the 6 individual's status, so if they were happy 7 with their valsartan and had -- as I shared 8 in my report in Section IV.E, they were happy 9 with their valsartan, they had serious health 10 issues, they may have even tried alternative 11 medications and felt that the valsartan was 12 the best at controlling their hypertension, 13 and contextual factors, how much their 14 relationship with their doctor and their 15 ability or inability to have a healthy 16 lifestyle, all of those factors would have an 17 impact on what they thought the drug was 18 worth. 19 BY MR. DAVIS: 20 Q. Okay. But you're not answering 21 my question. 22 My question is, if there's no 23 supply after the recall, as you can see from 24 the sales data, even if a consumer -- like</p>

<p style="text-align: right;">Page 198</p> <p>1 let's just assume that there is a consumer 2 who does want ZHP valsartan after the recall 3 and wants to go get a new prescription of it 4 from their doctor, the result is just like it 5 was with Fen-Phen, they can't get it, right? 6 A. I'm assuming that is the case, 7 yes. 8 Q. And they would end up, 9 therefore, paying no money for it, correct? 10 A. Yes. 11 Q. Okay. Thank you. 12 And there would be no 13 intersection of -- sorry, showing you my 14 screen, you've got it right there. 15 A. Yes. 16 Q. There would be no intersection 17 of supply and demand in that very specific 18 situation I just asked you about, correct? 19 A. Correct. 20 Q. Okay. Thank you. 21 A. Should I put these away? 22 Q. Sure. 23 A. Okay. 24 MR. DAVIS: I'm marking</p>	<p style="text-align: right;">Page 200</p> <p>1 what is in this label period, so I don't know 2 how to understand the absence of the two 3 impurities you just mentioned. 4 Q. Well, I'm not asking you yet to 5 understand the absence of them. I'm just 6 asking you if you see any reference to them 7 in that document. 8 A. I cannot do that. You're 9 asking if there's any reference, and I don't 10 know if there's any reference without having 11 a chance to review the document. 12 Q. Okay. So you're not willing to 13 take my word for it that they're not in 14 there? You're willing to look. Why don't 15 you take a look, that's fine. 16 Do you want to look at -- and I 17 can direct your attention, for example, to 18 make this go a little faster, okay, if you 19 don't mind, go to the very last page. 20 Do you see that last question 21 there, "What are the ingredients in Diovan?" 22 A. I do. 23 Q. Okay. Do you see any reference 24 to NDEA, NDMA?</p>
<p style="text-align: right;">Page 199</p> <p>1 Exhibit 9. 2 (Whereupon, Keller Exhibit 3 Number 9 was marked for 4 identification.) 5 BY MR. DAVIS: 6 Q. This is a -- can you identify 7 this document for me? 8 A. No. 9 Q. I'll represent to you that it's 10 a valsartan -- I'll represent to you that 11 it's a valsartan label, which may or may 12 not -- I think, we looked at your materials 13 considered. 14 Is this a document you recall 15 seeing ever? 16 A. No. 17 Q. Okay. I'll represent to you -- 18 but, you know, you're free to look, but I'll 19 represent to you that there's no mention of 20 nitrosamines, NDMA, NDEA, anywhere in this 21 label. 22 Are you willing to accept that, 23 or do you want to take a look? 24 A. I actually don't have any idea</p>	<p style="text-align: right;">Page 201</p> <p>1 A. I am not a chemist. I don't 2 know the different forms and labels. Those 3 drugs may be represented some other way. I 4 cannot answer the question. 5 Q. Would you agree with me -- 6 let's start with just a very general 7 proposition. 8 Would you agree with me that a 9 manufacturer of valsartan when they 10 distribute it into the US market, by calling 11 it valsartan and by distributing this label 12 with it, they're conveying some kind of 13 message to the people that will interact with 14 it, namely physicians and consumers, correct? 15 MR. GOLDBERG: Objection to 16 form. Foundation. 17 A. Please be more specific. 18 BY MR. DAVIS: 19 Q. Do you think that by -- when a 20 manufacturer of valsartan distributes 21 valsartan in the US market, by calling it 22 valsartan, are they conveying a message that 23 it's valsartan? It's a pretty general 24 proposition, right?</p>

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1 A. They're saying it's valsartan.
2 I'm not going to speak to what that means to
3 consumers, or physicians or anybody else.
4 Q. But there's a message embedded
5 in there, right, that this is valsartan,
6 correct?
7 A. I am not an expert on the drug
8 ingredients, and I don't know what that
9 communication would mean.
10 All I'm willing to acknowledge
11 is if they say it's valsartan, that that may
12 have meaning, and different meanings to
13 different people. I am not an expert on
14 valsartan, and I cannot give you an opinion.
15 Q. Sure.
16 And let's excise that from the
17 question, which by that I mean whatever
18 valsartan means, by calling it valsartan, the
19 manufacturer is conveying a message that it's
20 valsartan, whatever that means, right?
21 A. I'm just -- I am always
22 representing the consumer point of view, and
23 valsartan would just have different meanings
24 for different consumers based on the

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1 different messages and the context in which
2 these, you know, messages and drugs were
3 taken.
4 So I don't want to give the
5 impression that if there was a term valsartan
6 that all consumers would derive the same
7 meaning from it.
8 Q. Well, I'm not talking about the
9 recipient of the message right now. I'm
10 talking about the entity delivering the
11 message.
12 I'm saying that -- what I'm
13 asking you is do you agree that by calling it
14 valsartan, the manufacturer that calls it
15 valsartan is intending to convey a message
16 that it's valsartan, whatever that means?
17 A. Okay.
18 Q. You don't take any issue with
19 that, right? It's a pretty simple
20 proposition.
21 A. I don't like answering
22 questions that end in "whatever it means."
23 That's just my comfort level.
24 Q. Whatever valsartan means. I'm

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1 trying to --
2 A. I understand.
3 Q. I heard what you said about
4 that.
5 A. I understand.
6 Q. So what I'm trying to do is
7 just focus on a very simple question here.
8 And is there anything about
9 that that you disagree with, that a
10 manufacturer is not attempting to convey the
11 message that this is valsartan by calling it
12 valsartan, whatever that term valsartan
13 means?
14 A. Okay.
15 Q. And similarly with Exhibit 9
16 we're looking at, this label, prescribing
17 information, there's a message there, or
18 multiple messages in fact, but they all
19 relate to valsartan, correct?
20 A. Now I will need to read the
21 document. I anticipated this.
22 Q. You don't think that this
23 document that has to do with valsartan
24 conveys a message about valsartan, or

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1 multiple messages? It's a pretty simple
2 question.
3 A. I cannot answer that question.
4 I mean, if you're just saying is there
5 communication about valsartan in here? I
6 would say yes. For me, a message has a
7 different meaning, and I would need to read
8 the document to understand what the
9 message -- multiple messages might be.
10 Q. Okay. Let's go back to your
11 report for a moment, and again that section E
12 that's titled Real-world evidence indicates
13 that the at-issue VCDs held value.
14 A. Yes.
15 Q. And I understand you have --
16 you know, and I'm going to try and
17 short-circuit a long back and forth here by
18 stating that I understand that you have quite
19 a few sources of general applicability here
20 to support what you're saying amounts to
21 real-world evidence of value.
22 My question very specifically
23 here is, what evidence from this fact
24 situation and case specifically, what

<p style="text-align: right;">Page 206</p> <p>1 valsartan-specific evidence do you have that 2 is real-world evidence that indicates that 3 the VCDs at issue had value? 4 A. I have evidence from the 5 individual depositions from the plaintiffs, 6 and I have quoted some of them, who said that 7 the at-issue VCDs provided them with 8 therapeutic benefit. 9 I want to qualify, this is a 10 small subset of depositions. I know that 11 there were probably thousands if not tens of 12 thousands consumers who took valsartan and 13 this is a small group. But this is one 14 source of evidence that consumers who took 15 the at-issue valsartan said that -- some of 16 them, not all of them -- that it helped them 17 with controlling their blood pressure, that 18 they had fewer side effects such as 19 light-headedness and dizziness and nausea, 20 and that they did not suffer any extreme 21 emotional consequences to the point of 22 actually seeking professional help. So those 23 are just some examples of value from the 24 real-world evidence.</p>	<p style="text-align: right;">Page 208</p> <p>1 VCDs held value. 2 Q. Anything else, or those two? 3 A. I will also add -- thank you 4 for asking -- the FDA also mentioned that 5 consumers or patients who were taking the 6 at-issue VCDs should not stop taking the 7 VCDs, thereby indicating that they held 8 value, unless, you know, an alternative was 9 available to them. So that is also a source. 10 So I appreciate your giving me 11 a chance. 12 Q. Sure. 13 So you've identified those 14 three things. Is that everything? 15 A. To the best of my recall. 16 Q. Sure. Okay. Well, let's, I 17 guess, take them somewhat in order. 18 You concede, you know, for the 19 first point, which is the plaintiff 20 depositions, you do concede at paragraph 52 21 that in your view "The statements of 22 consumers, particularly those...in 23 litigation, regarding their retrospective 24 valuation of at-issue VCDs may not be</p>
<p style="text-align: right;">Page 207</p> <p>1 I also -- the other sources of 2 value also come from information in the 3 public press as well as in some of the 4 depositions, in the individual plaintiff 5 depositions, where physicians are either 6 publicly recommended, for example, I believe 7 Dr. Neeson, to AARP group members that, you 8 know, they should not stop taking the 9 at-issue VCDs on their own without talking to 10 their physicians because it is more important 11 to control their blood pressure, and they 12 could face very serious consequences, health 13 consequences if they stopped, and that it 14 would be -- the trade-off would be -- even if 15 there were any problems in the short or the 16 long-term with regard to any of the potential 17 cancers, which again would vary across 18 individuals, that the immediate serious 19 health consequence of stopping their at-issue 20 VCDs would be serious. 21 So the sources, just to sum, 22 are the plaintiff depositions as well as -- 23 as well as physicians. This includes 24 cardiologists who shared that the at-issue</p>	<p style="text-align: right;">Page 209</p> <p>1 reliable measures of even individual value 2 assessments," right? 3 A. I will say yes and no. 4 Q. Why are you saying yes and no 5 to something you wrote in your report? 6 A. Again, because of the context 7 in which you are reading out that one 8 sentence, and I'm going to do the following 9 sentence, which is -- okay, so I read it so I 10 don't have to go through the -- this will be 11 more efficient. 12 "Nonetheless, testimony of 13 several consumer-plaintiffs in this case 14 corroborates this post-awareness value for 15 the at-issue VCDs," and then we have a quote 16 from Samuel Cisneros. I hope I didn't 17 butcher that. 18 And "Additionally, many other 19 consumers that even with their current 20 knowledge of the impurities, the VCDs they 21 took were effective in treating their 22 hypertension." 23 Q. Since you called out 24 Mr. Cisneros particularly, I'm going to mark</p>

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1 Exhibit 10 here.
2 (Whereupon, Keller Exhibit
3 Number 10 was marked for
4 identification.)
5 BY MR. DAVIS:
6 Q. Did you read the entirety of
7 Mr. Cisneros' deposition?
8 A. I did.
9 Q. Did you read the entirety of
10 every class rep deposition that you cite in
11 your materials considered?
12 A. I read some of them, and I
13 reviewed the rest.
14 Q. How did you make a decision
15 about which ones to read in their entirety
16 and which ones to read portions of?
17 A. I used a couple of different
18 selection criteria. I was -- in alignment
19 with my MICI framework, I was looking for
20 different types of individuals, you know,
21 male, female, race, education, just to get
22 some variety or variance in those individual
23 characteristics.
24 I also, for contextual

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1 variance, I looked at things like whether
2 they were smokers or drank alcohol or
3 consumed red meat, so just to give you an
4 example of my methodology.
5 So I selected as -- like a
6 researcher, I tried to select different types
7 of consumers in the set of depositions.
8 Q. Were you provided the full
9 transcripts, or were you provided some full
10 transcripts and some incomplete transcripts?
11 A. I was provided the full
12 transcripts.
13 Q. Okay. And I get -- I hear what
14 you're saying, that you tried to review some
15 of them based on varying individual
16 characteristics.
17 How did you decide which of
18 those to review in full and which of those to
19 review selections of?
20 A. I -- once I started looking and
21 I started reading it, if I thought it was
22 interesting I read the whole thing.
23 I will admit that sometimes,
24 you know, if it was shorter I was more

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1 motivated, if it was 173 pages versus 349
2 pages.
3 And at other times I felt, you
4 know, I was not getting any new insights or
5 information, so then I would just review the
6 rest of the document.
7 Q. Okay. I mean, we're talking
8 about thousands upon thousands of pages of
9 testimony here, right?
10 A. I am aware. I don't want to
11 say -- I'm not going to multiply or give you
12 a number, but I know that there were over 40
13 depositions, and the range was typically
14 anywhere from like 150, 160 pages to like 350
15 or 400-plus pages, so yes.
16 Q. Okay. So many thousands of
17 pages?
18 A. Correct.
19 Q. So would you have reviewed
20 page 99 of Mr. Cisneros' deposition that I
21 have for you there? Do you see where he says
22 on lines 11 through 13, "[REDACTED]"
23 "[REDACTED]"
24 "[REDACTED]."

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1 Do you see that?
2 A. Yes, I do.
3 Q. Does that sound like someone
4 who would pay a dime for contaminated
5 valsartan?
6 A. [REDACTED]
7 [REDACTED], which I'm
8 going to object to now because I don't
9 believe that that is necessarily the message
10 that he was given, "[REDACTED]"
11 "[REDACTED]" is not saying that he did
12 not get any value from it. Because I just
13 quoted something in my report that said [REDACTED]
14 [REDACTED]
15 [REDACTED].
16 Q. Right. So let me see if I
17 understand what you're saying.
18 You're drawing a distinction
19 between therapeutic value and economic value,
20 right?
21 A. In part correct. I am saying
22 that the value or worth of a drug will vary
23 by consumers who are going to compare the
24 benefits, and that includes therapeutic

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1 benefits just like you describe, and the
2 costs of the drug, and that includes price.
3 So you have many other
4 variables going on simultaneously on the
5 benefit and the cost side in order to make an
6 assessment of value.
7 Q. And for you that's therapeutic
8 value in the context that we're talking about
9 right here with Mr. Cisneros?
10 A. All I'm saying is as a
11 researcher who is looking at this, I would
12 not assume the value is zero or the drug is
13 worth nothing to him because [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 And even though what I just
19 read is -- [REDACTED]
20 [REDACTED] it does not mean that the calculation
21 of what the drug is worth is zero.
22 Q. Do you have any reason to doubt
23 [REDACTED]
24 [REDACTED]

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1 A. I don't have any context to
2 answer that question.
3 Q. Then you -- back to your
4 report, you provide a citation, this is
5 paragraph 52, to it looks like about a dozen
6 or so class reps, right?
7 A. Yes.
8 Q. Okay. Did you read all of
9 those transcripts in their entirety?
10 A. I read or reviewed all of them.
11 Q. Okay. So were you aware, for
12 example, that Eric Erwin in his deposition,
13 who is in your footnote here, that he stated
14 that non-contaminated VCDs wouldn't even hold
15 value for him if they came from a facility
16 that had issues?
17 A. I don't recall that exact
18 statement, but I'll take your word for it.
19 And it supports my general
20 premise that different consumers will take
21 into account different message variables,
22 their individual differences will lead them
23 to put weights on different pieces of
24 information, and the context in which that

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1 they are making this decision, that includes
2 not only their physician but their diet and
3 lifestyle, would all have an impact on how
4 they would use either a compensatory or
5 non-compensatory decision.
6 So I mean just go back to this
7 footnote. Part of what I learned from
8 reading and reviewing these plaintiff
9 depositions was the fact that many of the
10 variables that I've just mentioned, the
11 message, the individual difference, and the
12 context, were all part of the ecosystem or
13 the wholistic inputs into thinking about the
14 drug.
15 Q. Okay. You also refer to a
16 Mr. Dennis Kaplan's testimony in your
17 footnote there. Did you read at page 145 of
18 his deposition that "they should never have
19 enabled it to be out in the market where I
20 and other people could have taken it"? Did
21 you read that portion of his deposition?
22 A. Again, I don't recall that
23 exact thing, but I believe you. If you are
24 stating that was in his deposition, I believe

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1 you.
2 And again, just your last two
3 examples showed how much variance there is in
4 how consumers would respond to this
5 information.
6 Q. What about page 18 of Mary
7 McLean's deposition where she says, "I
8 wouldn't have taken it knowing that it was
9 contaminated." Do you recall reading that?
10 A. Again, I do not recall
11 specifically, but it does -- it does not go
12 against my premise that consumers will have a
13 range of reactions to the recall.
14 Q. Okay. But you're citing these
15 people in particular to say that they
16 acknowledged it had value, but they're all
17 telling you -- or they're all telling under
18 oath that it had no economic value for them,
19 that they wouldn't have purchased it, right?
20 A. I'm sorry to repeat this again.
21 Value equals benefit minus cost. They're
22 acknowledging there was therapeutic benefit.
23 That means something positive. Even if some
24 of them are acknowledging that there is no

<p style="text-align: right;">Page 218</p> <p>1 economic value, one cannot assume that the 2 sum or the difference between all of their 3 benefits and costs would equal not only 4 uniform, but would equal zero. 5 Q. I want you to -- and I hear 6 what you're saying regarding therapeutic 7 benefit, that there's -- your assertion is 8 that there's therapeutic value here and that 9 has to be accounted for, right? 10 A. My assertion is that there are 11 benefits and costs that need to be assessed 12 in order to make a determination of worth, 13 and therapeutic benefit is one example of 14 benefit. 15 Q. So let me ask you to -- I'm 16 going to set forth a hypothetical for you, 17 and I want -- I'm going to walk through it 18 step-by-step, and indulge me here, if you 19 don't mind. 20 I want you to assume that for 21 all of the at-issue VCDs, that they were all 22 adulterated. 23 Do you follow me there? 24 A. Okay.</p>	<p style="text-align: right;">Page 220</p> <p>1 that for me. I know you disagree with it, 2 but I want you to assume that with me, right? 3 Okay? 4 A. Okay. 5 Q. Assuming those things, would 6 you not agree that the value of these drugs 7 is zero dollars? 8 A. I disagree. 9 Q. Okay. How do you disagree with 10 that? 11 A. As I said, there is a set of 12 benefits. The therapeutic benefits is just 13 one benefit. So saying to me that there is 14 no therapeutic benefit just makes the value 15 of therapeutic benefits in the set of 16 benefits zero, but not the other benefits. 17 When you say it's unavailable 18 and the price is zero, yes, there is no 19 economic price or cost in the set of costs, 20 but there are many other costs. 21 So again, the remaining, not 22 the therapeutic value which you asked me to 23 assume is zero, and not the price that you 24 asked me to assume is zero, there are other</p>
<p style="text-align: right;">Page 219</p> <p>1 Q. Okay. And as I showed you in 2 the US Code exhibit I showed you, 21 USC 331, 3 I showed you that it's illegal to distribute 4 adulterated drugs, right? 5 A. That's the document I did not 6 have a chance to review, is that correct? 7 Are you referring to Exhibit 9? 8 Q. I'm referring to Exhibit 7 9 here. 10 A. Oh, I'm so sorry. 11 Okay. That's also a document 12 that I did not review completely, and you 13 just read the first page. 14 Q. Well, indulge my hypothetical 15 here, that all the at-issue VCDs here were 16 adulterated, and indulge me also that it was 17 illegal to sell those adulterated drugs, for 18 example, under 21 USC 331 or Exhibit 7. 19 Do you follow me so far? 20 A. Mm-hmm. 21 Q. I want you to also assume that 22 these VCDs are economically worthless at the 23 point of sale regardless of any medical 24 benefit they provide. I want you to assume</p>	<p style="text-align: right;">Page 221</p> <p>1 variables in this equation that would 2 determine worth. 3 Q. I think you misheard the third 4 part there. Let me try it again. 5 So I've got -- I think we're 6 through two points, right, in this 7 hypothetical, which is that all the at-issue 8 VCDs here are adulterated, that the sale of 9 those drugs would have been prohibited under 10 the law, correct? 11 A. Correct. 12 Q. Okay. Meaning that there would 13 have been no supply of them in the market, 14 and no ability for consumers to purchase 15 them, right? 16 A. Okay. 17 Q. Okay. And then I want you to 18 assume that the value of those drugs from an 19 economic standpoint as applied to -- that 20 every single person was found to have derived 21 zero economic value from these drugs 22 regardless of the medical benefit they may 23 have provided. 24 Do you follow me?</p>

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1 A. I do follow you, and I
2 disagree. I cannot -- I cannot respond
3 because I disagree with the basic premise.
4 Q. Okay. So, well, let me show
5 you something then.
6 Well, follow me through. I
7 know you disagree with the premise.
8 A. Okay.
9 Q. But follow me through here.
10 A. Okay.
11 Q. And let's just take it as a
12 fact, even if you disagree with that fact,
13 that for every single consumer of these drugs
14 that there was zero economic value for them
15 at the time of sale, that the drugs were
16 economically worthless at the time of sale
17 regardless of any medical benefit to be
18 derived from them. Assume that for me, that
19 that applies to everyone.
20 Would you not agree that,
21 assuming those things, that the value of the
22 drugs in that case would be zero dollars,
23 granted that you disagree with the premise?
24 MR. GOLDBERG: Objection to

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1 form. Foundation.
2 A. I'm going to go back to my
3 formula and say that there will be a range of
4 consumers, and I have this information in my
5 report, actually throughout my report, so I
6 can't even tell you which section of IV this
7 would belong to, but that there would be a
8 range of consumers who would say that the
9 drug had value to me, or has value to me --
10 even if they cannot get it, that the drug has
11 value to me because I did not have side
12 effects; the drug has value to me because I
13 had peace of mind; the drug had value to me
14 because I could take it in a single pill
15 form.
16 And I'll go to the cost side,
17 not paying anything, as you said, that I
18 don't -- the drug had value to me because it
19 was familiar and now I have to learn about
20 another drug; the drug has value to me
21 because now I have to go and talk to my
22 physician about another prescription; the
23 drug has value to me because -- okay.
24 I'll stop there. So you got my

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1 general idea.
2 BY MR. DAVIS:
3 Q. Sure. And I'm trying to
4 exclude that from this hypothetical, and I
5 know you disagree with the premise, I know
6 you do, and you've articulated that. But
7 just follow me through with the premise here,
8 which is that it's been determined for every
9 single one of these consumers who you just
10 posited a list of questions they might ask or
11 opinions they may have, just assume for me
12 that it's been determined that the drugs are
13 economically worthless for them regardless of
14 all that stuff.
15 Do you follow me?
16 A. Yes.
17 Q. Okay. And in that situation,
18 combine that with the fact that all the drugs
19 are posited to have been adulterated and
20 therefore illegally sold, couldn't have
21 gotten them, couldn't have paid anything for
22 them, at that point, with all those premises
23 and stuff that you don't agree with, but just
24 follow me through, would you agree with me at

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1 that point, if all those things were true,
2 which I get you don't agree with, that the
3 drugs would have no value at that point,
4 economic value?
5 A. Whoever made that determination
6 was wrong.
7 Q. Okay.
8 MR. DAVIS: I'm going to mark
9 an exhibit here.
10 MR. GOLDBERG: John, do you
11 want to take a minute break? We've
12 been going another 90 minutes.
13 MR. DAVIS: I just want to
14 finish this real fast, and then I'm
15 close to being done, to be honest.
16 MR. GOLDBERG: Okay. Got it.
17 MR. DAVIS: I'll probably want
18 to take a quick break just to go
19 through my notes.
20 MR. GOLDBERG: Sure. Got it.
21 MR. DAVIS: I'm going to mark
22 Exhibit 11.
23 (Whereupon, Keller Exhibit
24 Number 11 was marked for

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1 identification.)
2 BY MR. DAVIS:
3 Q. Just to pick up where we left
4 off, you testified to me that you thought
5 that that person who made that determination
6 would be wrong, correct?
7 A. Yes.
8 Q. Okay. Do you understand that
9 the Court is that person that's made that
10 determination in this case?
11 MR. GOLDBERG: Objection to
12 form. Foundation, mischaracterizes
13 the document.
14 BY MR. DAVIS:
15 Q. Why don't you flip to --
16 MR. GOLDBERG: You're marking
17 this as --
18 MR. DAVIS: This is Exhibit 11,
19 I believe.
20 BY MR. DAVIS:
21 Q. I want you to turn to page 20
22 of the document. The numbering is very small
23 in the top right corner.
24 A. And again, I haven't had time

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1 to review this document.
2 MR. GOLDBERG: Somehow we're
3 going to have to figure out what you
4 want to do here. She hasn't reviewed
5 the document. I know you want to ask
6 her about page 20.
7 MR. DAVIS: I don't really have
8 much to ask her. I just want to --
9 MR. GOLDBERG: I think you
10 should explain to her what the
11 document is, and give her a second to
12 at least scan it for a minute or two
13 so she can get familiar with the
14 document.
15 BY MR. DAVIS:
16 Q. I will represent to you this is
17 an opinion that the Court has issued in this
18 case, a written opinion. Do you see the case
19 header up there, "In Re: Valsartan"?
20 A. I see that.
21 Q. And do you see that on the
22 right in bold there it says, "MTD Opinion 3:
23 Warranty Claims"?
24 A. Yes.

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1 Q. You then you see "Kugler,
2 United States District Judge"?
3 A. Yes.
4 Q. Okay. And in fact, that blue
5 version at the top -- sorry, it's blue in my
6 version, but it printed black and white, but
7 you'll see the case number information, Case
8 1:19-md-2875, document number 775, filed on
9 to the docket January 22, 2021.
10 Do you see that?
11 A. Yes.
12 Q. Okay. So I'll represent to you
13 that this is an opinion of the Court that's
14 been entered into this case. And I just want
15 to -- I'm not going to ask you any detailed
16 questions about it, but on page 20 --
17 A. Sorry for clarification. So
18 when you say "an opinion of the Court," is
19 that the same thing as the opinion of the
20 judge?
21 Q. Yes, yes. The judge's order.
22 A. Thank you.
23 Q. And on page 20 the Court says,
24 "This court finds that contaminated drugs are

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1 economically worthless at the point of sale
2 by virtue of the dangerousness caused by
3 their contamination, regardless whether the
4 sole VCDs actually achieved the medical
5 purpose of lowering blood pressure. Put
6 differently, contaminated drugs, even if
7 medically efficacious for their purpose,
8 cannot create a benefit of the bargain
9 because the contaminants, and their dangerous
10 effects, were never bargained for."
11 Do you see that?
12 A. Yes.
13 Q. And your testimony is you
14 disagree with that?
15 A. I did not testify that I
16 disagreed with this. I testified that I
17 disagreed with your example.
18 I will now say that I don't
19 know the context in which this determination
20 or this decision was made. I don't know what
21 other facts were provided to the Court or to
22 the judge. I am not a lawyer. And I don't
23 know what was the input for this decision,
24 and how -- what the laws are that helped make

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1 this determination, but to say that a drug is
2 worthless because it's -- let me read that
3 again, even if it is efficacious that the
4 economic value is zero is wrong.
5 Q. Okay. But you testified
6 earlier that you've never done an economic
7 damages analysis in litigation, have you?
8 A. Correct.
9 Q. And you've never done one
10 period, right?
11 A. Correct.
12 Q. Okay. And you're not an
13 economist, right?
14 A. I have a bachelor's in
15 economics, but I'm not an economist.
16 Q. All right. Thank you.
17 MR. DAVIS: Let's take a quick
18 break, five minutes, and I'm pretty
19 close.
20 MR. GOLDBERG: Okay.
21 MR. DAVIS: We can go off the
22 record.
23 THE VIDEOGRAPHER: Off the
24 record at 3:29.

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1 (Whereupon, a recess was
2 taken.)
3 THE VIDEOGRAPHER: Back on the
4 record at 3:46.
5 BY MR. DAVIS:
6 Q. I've just got ten more minutes
7 of questions maybe and one new document for
8 you.
9 So just to re-cover one area
10 very briefly, do you remember talking with me
11 about -- we were going back and forth about
12 the fact that there's a message embedded in
13 calling the product valsartan, whatever the
14 consumer made of that message or whatever the
15 term valsartan means, I think we agreed that
16 there was a message embedded in there, right?
17 A. My recall is that this was in
18 response to the document that you showed me
19 that's Exhibit 9 that I didn't review in
20 total, and that I said I would concede that
21 there is communication in there.
22 In my expertise on health
23 message processing, I could not make a
24 determination if there was a message in

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1 there.
2 Q. But there's a communication,
3 right?
4 A. There's some material, written
5 material in there.
6 Q. Okay. And your -- and I don't
7 want to overgeneralize here, but your whole
8 focus is oriented towards the consumer,
9 right? You look at things from a mostly
10 consumer standpoint, and that also includes
11 the physician, I suppose, but your whole
12 focus is sort of consumer-oriented, right?
13 A. I am an expert on how consumers
14 assess value or worth of products and
15 services they're considering, have consumed,
16 or want to continue consuming. And so yes,
17 from that perspective I'm focused on the
18 consumers' assessment of worthiness.
19 Q. Okay. Would you agree with me
20 that the communication that -- you know, and
21 I'll adopt your term here, communication --
22 that the communication of calling the drug
23 valsartan, that was a communication that
24 consumers really had no choice but to rely

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1 on, right?
2 A. Incorrect. It is very clear
3 that consumers have a lot of different
4 sources of communication from different
5 people, from -- in different formats, and
6 that who would seek what kind of information
7 in different times, in different formats
8 would depend on the individual. It would
9 need to be an individual inquiry.
10 Q. That's your opinion?
11 A. Yes.
12 Q. Okay. Well, flip to -- back to
13 Exhibit 11, if you don't mind.
14 A. Sure.
15 Q. And go to page 14.
16 A. Just give me a moment because I
17 can't see it. All right.
18 Q. Do you see in the last --
19 second to last full paragraph on that page it
20 starts with "The manufacturer's very naming
21 of the drug"?
22 A. Yes.
23 Q. It reads, "The manufacturer's
24 very naming of the drug as valsartan or

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1 valsartan-containing amounted to an express
2 warranty on which plaintiffs had no choice
3 but to 'rely' when they were prescribed the
4 drug and bought it as a medication for their
5 high blood pressure."
6 Do you see that?
7 A. Yes.
8 Q. Okay. And do you see that
9 that's part of this Court opinion that I
10 showed you earlier?
11 A. Yes.
12 Q. And you disagree with that?
13 A. I said I did not have an
14 opinion on that because I am not a lawyer and
15 I do not have all the information that was
16 presented to this Court before this
17 determination was made. I cannot agree or
18 disagree with this statement.
19 MR. DAVIS: Okay. I'm going to
20 mark Exhibit 12.
21 (Whereupon, Keller Exhibit
22 Number 12 was marked for
23 identification.)
24 ///

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1 BY MR. DAVIS:
2 Q. Do you recognize this as -- I
3 suppose it's not technically your invoice,
4 but it's Analysis Group's invoice to
5 Mr. Goldberg here.
6 Do you see that?
7 A. I do.
8 Q. Okay. And it includes -- it
9 includes the statement that this is just the
10 ZHP share of that invoice for 16.67 percent
11 of the total.
12 Do you see that on page 1?
13 A. I do. But I'll be honest with
14 you, I'm not sure exactly what that 16.6
15 refers to.
16 Q. Let me ask it a different way.
17 Did you prepare this invoice?
18 A. No, no.
19 Q. All right.
20 A. When you say "this," you're
21 talking about the page that you're just
22 referring to, right?
23 Q. Yes.
24 A. I don't know what's on the

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1 remaining pages.
2 Q. Did you actually send this
3 invoice to -- okay, somebody else did that?
4 A. I did not prepare or send the
5 invoice.
6 Q. You'll see on page 1 it says
7 that the invoice is "For professional
8 services rendered in connection with the
9 above referenced case for the period ending
10 December 31, 2021," right?
11 A. Yes.
12 Q. Okay. And your report was
13 signed on January 12th, correct?
14 A. Correct.
15 Q. And you've also done some work
16 on the case since that point, right?
17 A. Yes.
18 Q. You're sitting here today, for
19 example. Did you sit for any preparation
20 sessions?
21 A. Yes.
22 Q. Okay. About how many would
23 that be?
24 A. Sessions defined by what unit

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1 of time?
2 Q. Hours.
3 A. Hours.
4 Are you talking about
5 preparation that I did for the depo on my
6 own, or only in some other context?
7 Q. Sure. Any context.
8 What I'm trying to get at is
9 what your next invoice might look like.
10 A. I cannot -- I cannot give you
11 an exact number because I have not calculated
12 it.
13 Q. Do you think that it's -- for
14 example in this invoice you had billed -- you
15 personally had billed 37 hours. Do you think
16 it's more than that?
17 A. I don't want to guess. I'd
18 like to go back to my records to check.
19 Q. Okay. When do you anticipate
20 the next invoice being submitted to the
21 defendants in this case by Analysis Group?
22 A. Oh, I don't know when Analysis
23 Group would submit it.
24 Q. Do these invoices get sent out

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1 monthly or quarterly?
2 A. I don't know what their
3 procedure is.
4 Q. Okay. It says your rate here
5 is \$1,000 per hour, is that correct?
6 A. Yes.
7 Q. Okay. And then there's a
8 number of Analysis Group professionals that
9 are also listed here, correct?
10 A. Should I turn the page?
11 Q. Sure, on page 2, yeah.
12 A. Yes.
13 Q. Do you recognize all those
14 names?
15 A. Yes.
16 Q. How did you select those people
17 to work with on this report?
18 A. I did not select them to work
19 with me on the report. One of the members of
20 the team, Brian Ellman, got in touch with me
21 and asked me if I would be interested in
22 speaking to some lawyers about this case, and
23 I agreed, and I did so. And the lawyers
24 decided to retain me, and this team came as

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1 part of that.
2 Q. So you don't know who --
3 putting aside Mr. Ellman, all the names below
4 him, you don't know how those individuals
5 were assigned to your team?
6 A. No.
7 Q. Okay. Did you independently go
8 and vet any of their credentials?
9 A. No.
10 Q. Okay. And do the hour
11 allocations here on page 2 look accurate to
12 you, that you billed 37 hours, and this whole
13 team here billed 326 hours --
14 A. Well --
15 Q. -- up to this point?
16 A. -- I'm assuming it's accurate.
17 It's not something that I ever saw until this
18 document was presented to me.
19 Q. If you go to the third page,
20 the next page.
21 A. Yes.
22 Q. You'll see that this is your
23 line item of your work on the case, right?
24 A. Yes.

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1 Q. Did you write those narrative
2 entries there?
3 A. I did.
4 Q. And would that be the same
5 for -- to the best of your understanding,
6 maybe you don't have any idea, but for these
7 other individuals at Analysis Group, Ellman,
8 O'Laughlin, below, would they have written
9 their own narrative descriptions?
10 A. I have no idea.
11 Q. You have no idea.
12 You would expect they probably
13 would have, though?
14 A. I have no idea.
15 Q. So what did these Analysis
16 Group employees do for you on this case?
17 A. The short answer is that I use
18 them the way I use research assistants. As
19 you mentioned, I got the case -- not the
20 case, sorry.
21 I got the request to be an
22 expert witness and write a report late last
23 year, and that is when the students are on
24 break. And just like I use the students as

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1 research assistants, I did the same with the
2 AG team.
3 Q. Okay. Did that include them
4 writing any of your report in its draft form?
5 A. The way it works is I work on
6 the report, I ask them for collaborating or
7 supporting material on -- for my opinions, I
8 ask them to read those materials that I
9 provided and find similar materials to help
10 me make a list of the references that I might
11 want to cite or I might not want to cite.
12 And I also, you know, ask them
13 as they were going through this if they had
14 any ideas, you know, they're welcome to share
15 them. But at the end of the day it's my
16 report, I care about quality, and I accept or
17 reject, you know, any ideas from anyone.
18 Q. Okay. And your invoice, your
19 time here is complete, in your opinion, up
20 through December 31st?
21 A. I mean, I will say that I, as
22 in other cases, I don't put in time that's
23 related to thinking or abstract things that
24 are associated with some of the case

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1 preparation. And, yeah, so I will say it's
2 pretty accurate.
3 Q. Okay. But more tangible things
4 like actually writing the report, that would
5 something you would bill, right?
6 A. So reading, writing, revising,
7 editing, checking, searching for literature
8 myself, those would be tangible things.
9 Q. Why is it in your line items
10 for time that the first time the mention of
11 any draft report appears is on December 16,
12 2021 where you say you reviewed an already
13 existed draft report?
14 A. That's not how I interpret
15 "review." For me, as I mentioned earlier, as
16 a reviewer and an aid, I think of review as
17 creating drafts, revising drafts, editing
18 drafts, for me it's all part of a review
19 process.
20 Q. So what you're saying is you
21 may have miswritten the narrative here and
22 this is when you started writing the report,
23 December 16th?
24 A. No. From my perspective I'm

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1 not misrepresenting it. That's what review
2 means for me.
3 So, for example, if you use the
4 page that we're looking at, when I say
5 "Review of Conti Declaration and Protective
6 Order," 12/09, I'm already reviewing and
7 writing the report based on what I'm seeing
8 from Dr. Conti's declaration and thoughts in
9 response to the protective order.
10 When I say "Review of online
11 Valsartan recall materials," I'm already
12 writing parts of the report because I'm
13 thinking about -- I'm thinking about what
14 will go into forming my opinions in the
15 report that are connected with these
16 materials.
17 Q. Sure.
18 Go down to Mr. Ellman's hours
19 on page 4, the next page. He says on
20 December 10th that he had a call with the
21 case team and reviewed an outline.
22 Do you recall what he is
23 referring to by the "outline" there?
24 A. I do not.

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1 Q. Okay. Was that something that
2 was provided by counsel?
3 A. I do not know that.
4 Q. Okay. You'll see that a number
5 of the other Analysis Group employees do have
6 narrative line items regarding their work
7 drafting the report.
8 Take a look at Laura O'Laughlin
9 on page 4. For example, on December 8th she
10 says, "Assist in preparing expert report."
11 Do you see that?
12 A. Yes.
13 Q. Same thing on the 9th, same
14 thing on the 10th.
15 And then if you go down to Kate
16 Schoenbach, I believe -- I hope I pronounced
17 that right, she says she "assisted with
18 drafting," and then something is redacted
19 there for a number of days.
20 A. Correct.
21 Q. Okay. Same thing with
22 Mr. Jacob Eby, he says that he -- for
23 example, on December 13th he said he assisted
24 in drafting.

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1 A. Yes.
2 Q. And that's all prior to
3 December 16th where you first mention
4 reviewing a draft report, right?
5 A. As I mentioned earlier, for me,
6 I started writing the report, you know, and
7 thinking -- you know, thinking through what I
8 would be looking for during that first call
9 with counsel. And I continued doing it on
10 the 9th, on the 10th, on the 16th, on the
11 17th, on the dates that you see there.
12 MR. DAVIS: Okay. All right.
13 I believe that's all the questions I
14 have.
15 I will make a formal request
16 that when the next invoice is
17 submitted that that be produced to us
18 as soon as possible.
19 And thank you, Dr. Keller. I
20 appreciate your time today.
21 THE WITNESS: Thank you very
22 much, I appreciate it.
23 MR. GOLDBERG: Just give us a
24 two-minute break and we can figure out

<p style="text-align: right;">Page 246</p> <p>1 if we have any questions for 2 Dr. Keller. 3 MR. DAVIS: Sure. 4 THE VIDEOGRAPHER: Off the 5 record at 4:03. 6 (Whereupon, a recess was 7 taken.) 8 THE VIDEOGRAPHER: Back on the 9 record at 4:07. 10 MR. GOLDBERG: We have no 11 questions for Dr. Keller at this time. 12 Thank you. 13 MR. DAVIS: Okay. Thanks. 14 THE WITNESS: Thank you very 15 much, everyone. 16 THE VIDEOGRAPHER: Off record 17 at 4:07. 18 (Whereupon, the deposition was 19 concluded.) 20 21 22 23 24</p>	<p style="text-align: right;">Page 248</p> <p>1 INSTRUCTIONS TO WITNESS 2 3 Please read your deposition over 4 carefully and make any necessary corrections. 5 You should state the reason in the 6 appropriate space on the errata sheet for any 7 corrections that are made. 8 After doing so, please sign the errata 9 sheet and date it. It will be attached to 10 your deposition. 11 It is imperative that you return the 12 original errata sheet to the deposing 13 attorney within thirty (30) days of receipt 14 of the deposition transcript by you. If you 15 fail to do so, the deposition transcript may 16 be deemed to be accurate and may be used in 17 court. 18 19 20 21 22 23 24</p>
<p style="text-align: right;">Page 247</p> <p>1 COMMONWEALTH OF MASSACHUSETTS) 2 SUFFOLK, SS.) 3 I, MAUREEN O'CONNOR POLLARD, 4 Registered Diplomat Reporter and Notary 5 Public in and for the Commonwealth of 6 Massachusetts, do certify that on the 10th 7 day of March, 2022, at 9:19, the person 8 above-named was duly sworn to testify to the 9 truth of their knowledge, and examined, and 10 such examination reduced to typewriting under 11 my direction, and is a true record of the 12 testimony given by the witness. I further 13 certify that I am neither attorney, related 14 or employed by any of the parties to this 15 action, and that I am not a relative or 16 employee of any attorney employed by the 17 parties hereto, or financially interested in 18 the action. 19 In witness whereof, I have 20 hereunto set my hand this 14th day of March, 21 2022. 22 _____ 23 MAUREEN O'CONNOR POLLARD, NOTARY PUBLIC 24 CSR #149108</p>	<p style="text-align: right;">Page 249</p> <p>1 ----- 2 E R R A T A 3 ----- 4 PAGE LINE CHANGE 5 _____ 6 REASON: _____ 7 _____ 8 REASON: _____ 9 _____ 10 REASON: _____ 11 _____ 12 REASON: _____ 13 _____ 14 REASON: _____ 15 _____ 16 REASON: _____ 17 _____ 18 REASON: _____ 19 _____ 20 REASON: _____ 21 _____ 22 REASON: _____ 23 _____ 24</p>

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ACKNOWLEDGMENT OF DEPONENT

I, _____, do
Hereby certify that I have read the foregoing
pages, and that the same is a correct
transcription of the answers given by me to
the questions therein propounded, except for
the corrections or changes in form or
substance, if any, noted in the attached
Errata Sheet.

PUNAM ANAND KELLER, Ph.D. DATE

Subscribed and sworn
To before me this
_____ day of _____, 20____.

My commission expires: _____

Notary Public

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LAWYER'S NOTES

PAGE LINE

1	_____	_____
2	_____	_____
3	_____	_____
4	_____	_____
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6	_____	_____
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Exhibit 210

REDACTED

1 IN THE UNITED STATES DISTRICT COURT
2 DISTRICT OF NEW JERSEY
3 IN RE: VALSARTAN) MDL No. 2875
4 LOSARTAN, AND IRBESARTAN)
5 PRODUCTS LIABILITY)
6 LITIGATION) HON. ROBERT B. KUGLER
7)
8)
9 This Document Relates to)
10 All Actions)

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8 * CONFIDENTIAL INFORMATION *

9 SUBJECT TO PROTECTIVE ORDER

12 VIDEOTAPED DEPOSITION OF TIMOTHY E. KOSTY,
13 called by the Plaintiffs for examination, taken by
14 and before Ann Medis, RPR, CLR, CSR-WA, and Notary
15 Public in and for the Commonwealth of
16 Pennsylvania, via Zoom Videoconference, at the
17 offices of Duane Morris, 600 Grant Street, Suite
18 5010, Pittsburgh, Pennsylvania 15219, on Thursday,
19 February 24, 2022, commencing at 10:07 a.m.

<p style="text-align: right;">Page 2</p> <p>1 A P P E A R A N C E S</p> <p>2 On behalf of Plaintiffs</p> <p>3 (via Zoom)</p> <p>4 HONIK LLC</p> <p>5 BY: RUBEN HONIK, ESQUIRE</p> <p>6 1515 Market Street, Suite 1100</p> <p>7 Philadelphia, Pennsylvania 19102</p> <p>8 267.435.1300</p> <p>9 ruben@honiklaw.com</p> <p>10 (via Zoom)</p> <p>11 KANNER & WHITELEY, LLC</p> <p>12 BY: CONLEE WHITELEY, ESQUIRE</p> <p>13 LAYNE HILTON, ESQUIRE</p> <p>14 DAVID J. STANOCH, ESQUIRE</p> <p>15 701 Camp Street</p> <p>16 New Orleans, Louisiana 70130</p> <p>17 504.524.5777</p> <p>18 c.whiteley@kanner-law.com</p> <p>19 l.hilton@kanner-law.com</p> <p>20 d.stanoch@kanner-law.com</p> <p>21</p> <p>22 On behalf of Defendants Teva Pharmaceuticals USA, Inc.;</p> <p>23 Teva Pharmaceutical Industries, Ltd.; Actavis LLC; and</p> <p>24 Actavis Pharma, Inc.</p> <p>25</p> <p>GREENBERG TRAUIG, LLP</p> <p>BY: TIFFANY M. ANDRAS, ESQUIRE</p> <p>77 West Wacker Drive</p> <p>Suite 3100</p> <p>Chicago, Illinois 60601</p> <p>312.456.8400</p> <p>andrast@gtlaw.com</p> <p>(via Zoom)</p> <p>WALSH PIZZI O'REILLY FALANGA LLP</p> <p>BY: CHRISTINE I. GANNON, ESQUIRE</p> <p>LIZA WALSH, ESQUIRE</p> <p>Three Gateway Center</p> <p>100 Mulberry Street, 15th Floor</p> <p>Newark, New Jersey 07102</p> <p>973.757.1100</p> <p>cgannon@walsh.law</p> <p>lwalsh@walsh.law</p>	<p style="text-align: right;">Page 4</p> <p>1 A P P E A R A N C E S (Continued)</p> <p>2 On behalf of Defendants Zhejiang Huahai Pharmaceutical</p> <p>3 Co., Ltd.; Prinston Pharmaceutical, Inc.; Huahai U.S.,</p> <p>4 Inc.; and Solco Healthcare U.S., LLC</p> <p>5 DUANE MORRIS LLP</p> <p>6 BY: DREW T. DORNER, ESQUIRE</p> <p>7 REBECCA BAZAN, ESQUIRE (via Zoom)</p> <p>8 DANA B. KLINGES, ESQUIRE (via Zoom)</p> <p>9 ALEK SMOLJI, ESQUIRE (via Zoom)</p> <p>10 30 South 17th Street</p> <p>11 Philadelphia, Pennsylvania 19103</p> <p>12 215.979.1000</p> <p>13 dtdorner@duanemorris.com</p> <p>14 rebazan@duanemorris.com</p> <p>15 dklinges@duanemorris.com</p> <p>16 asmolji@duanemorris.com</p> <p>17 On behalf of Defendant Humana Pharmacy, Inc.</p> <p>18 (via Zoom)</p> <p>19 FALKENBERG IVES LLP</p> <p>20 BY: MEGAN A. ZMICK, ESQUIRE</p> <p>21 230 W. Monroe Street, Suite 2220</p> <p>22 Chicago, Illinois 60606</p> <p>23 312.566.4808</p> <p>24 maz@falkenbergives.com</p> <p>25</p> <p>On behalf of Defendants H.J. Harkins Co., Inc. and</p> <p>Sciengen Pharmaceuticals Inc.</p> <p>(via Zoom)</p> <p>HINSHAW & CULBERTSON LLP</p> <p>BY: GEOFFREY M. COAN, ESQUIRE</p> <p>53 State Street, 27th Floor</p> <p>Boston, Massachusetts 02109</p> <p>617.213.7047</p> <p>gcoan@hinshawlaw.com</p>
<p style="text-align: right;">Page 3</p> <p>1 A P P E A R A N C E S (Continued)</p> <p>2 On behalf of Defendant Albertsons Pharmacy</p> <p>3 (via Zoom)</p> <p>4 BUCHANAN INGERSOLL & ROONEY, PC</p> <p>5 BY: CHRISTOPHER B. HENRY, ESQUIRE</p> <p>6 227 West Trade Street, Suite 600</p> <p>7 Charlotte, North Carolina 28202</p> <p>8 704.444.3475</p> <p>9 christopher.henry@bipc.com</p> <p>10</p> <p>11 On behalf of Defendants CVS Pharmacy and Rite Aid</p> <p>12 (via Zoom)</p> <p>13 BARNES & THORNBURG, LLP</p> <p>14 BY: KARA KAPKE, ESQUIRE</p> <p>15 2029 Century Park East, Suite 300</p> <p>16 Los Angeles, California 90067</p> <p>17 310.284.3766</p> <p>18 kara.kapke@btlaw.com</p> <p>19</p> <p>20 On behalf of Defendant Mylan Laboratories</p> <p>21 (via Zoom)</p> <p>22 PIETRAGALLO GORDON ALFANO BOSICK &</p> <p>23 RASPANTI, LLP</p> <p>24 BY: FRANK H. STOY, ESQUIRE</p> <p>25 One Oxford Centre</p> <p>301 Grant Street, 38th Floor</p> <p>Pittsburgh, Pennsylvania 15219</p> <p>412.263.4397</p> <p>FHS@pietragallo.com</p>	<p style="text-align: right;">Page 5</p> <p>1 A P P E A R A N C E S (Continued)</p> <p>2 On behalf of Defendant Amerisource Bergen</p> <p>3 (via Zoom)</p> <p>4 ULMER & BERNE LLP</p> <p>5 BY: JEFFREY D. GEOPPINGER, ESQUIRE</p> <p>6 312 Walnut Street, Suite 1400</p> <p>7 Cincinnati, Ohio 45202</p> <p>8 513.698.5038</p> <p>9 jgeoppinger@ulmer.com</p> <p>10</p> <p>11 On behalf of Defendant McKesson Corporation</p> <p>12 (via Zoom)</p> <p>13 NORTON ROSE FULBRIGHT US LLP</p> <p>14 BY: ELIZABETH NORRIS, ESQUIRE</p> <p>15 2200 Ross Avenue, Suite 3600</p> <p>16 Dallas, Texas 75201</p> <p>17 214.855.8074</p> <p>18 ellie.norris@nortonrosefulbright.com</p> <p>19</p> <p>20 On behalf of Defendant Optum, Inc.</p> <p>21 (via Zoom)</p> <p>22 DORSEY & WHITNEY LLP</p> <p>23 BY: SHEVON D.B. ROCKETT, ESQUIRE</p> <p>24 51 West 52nd Street</p> <p>25 New York, New York 10019</p> <p>212.415.9357</p> <p>rockett.shevon@dorsey.com</p> <p>On behalf of Defendant Cigna Corporation</p> <p>(via Zoom)</p> <p>HUSCH BLACKWELL LLP</p> <p>BY: A. JAMES SPUNG, ESQUIRE</p> <p>190 Carondelet Plaza, Suite 600</p> <p>St. Louis, Missouri 63105</p> <p>314.480.1500</p> <p>james.spung@huschblackwell.com</p>

<p style="text-align: right;">Page 6</p> <p>1 A P P E A R A N C E S (Continued)</p> <p>2 On behalf of Defendant Cardinal Health Inc.</p> <p>3 (via Zoom)</p> <p>4 CROWELL & MORING LLP</p> <p>5 BY: DANIEL T. CAMPBELL, ESQUIRE</p> <p>6 1001 Pennsylvania Avenue, NW</p> <p>7 Washington, DC 20004</p> <p>8 202.624.2544</p> <p>9 dcampbell@crowell.com</p> <p>10</p> <p>11 Also present</p> <p>12</p> <p>13 Matt Martin, videographer</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 8</p> <p>1 * INDEX OF KOSTY EXHIBITS (Continued) *</p> <p>2 NO. DESCRIPTION PAGE</p> <p>3 Exhibit 11 Chang, et al., article National 298</p> <p>4 Rates of Nonadherence to</p> <p>5 Antihypertensive Medications Among</p> <p>6 Insured Adults With Hypertension, 2015</p> <p>7 Exhibit 12 Article "Gianforte signals support 323</p> <p>8 for state pay plan proposal"</p> <p>9 Exhibit 13 Montana University System Summary 324</p> <p>10 Plan Description, Effective 7/1/21</p> <p>11 Exhibit 14 Analysis Group invoices for 333</p> <p>12 services performed in the case</p> <p>13 Exhibit 15 Excel spreadsheet containing 356</p> <p>14 amounts invoiced for services</p> <p>15 performed by Analysis Group and</p> <p>16 T. Kosty</p> <p>17 Exhibit 16 ASHP Guidelines on the Pharmacy 342</p> <p>18 and Therapeutics Committee and the</p> <p>19 Formulary System</p> <p>20 Exhibit 17 Expert Report of Kali Panagos, 352</p> <p>21 Pharm.D., R.Ph.</p> <p>22 Exhibit 18 Orange Book Preface, Food and Drug 357</p> <p>23 Administration Center Drug Evaluation</p> <p>24 and Research, Approved Drug Products</p> <p>25 for Therapeutic Equivalence</p> <p>Evaluations</p> <p>----</p>
<p style="text-align: right;">Page 7</p> <p>1 * I N D E X *</p> <p>2 TIMOTHY E. KOSTY PAGE</p> <p>3 EXAMINATION BY MR. HONIK 10, 339, 368</p> <p>4 EXAMINATION BY MR. STANOCH 209</p> <p>5 EXAMINATION BY MS. ANDRAS 365</p> <p>6 * INDEX OF KOSTY EXHIBITS *</p> <p>7 NO. DESCRIPTION PAGE</p> <p>8 Exhibit 1 Expert Report of Timothy E. Kosty, 25</p> <p>9 January 12, 2022</p> <p>10 Exhibit 2 Letter, 6/16/20, from S. Johnston 90</p> <p>11 to Judge Schneider, Re: In re</p> <p>12 Valsartan, Losartan and Irbesartan</p> <p>13 Product Liability Litigation</p> <p>14 Exhibit 3 MTD Opinion 3: Warranty Claims 106</p> <p>15 Exhibit 4 21 U.S.C.A. § 331 117</p> <p>16 Exhibit 5 FDA Warning Letter, 11/29/18, to 137</p> <p>17 ZHP</p> <p>18 ZHP01344159 - 01344164</p> <p>19 Exhibit 6 Expert Declaration of Rena 158</p> <p>20 Conti, Ph.D.</p> <p>21 Exhibit 7 Express Scripts Part D Medicare 231</p> <p>22 and Medicaid Policy</p> <p>23 Express_Scripts_1120_00000253</p> <p>24 Exhibit 8 CVS and Target Document Retention 233</p> <p>25 and Confidential Pharmacy Records</p> <p>Retention and Storage</p> <p>CVS_MDL2875_0000000208 - 0000000214</p> <p>Exhibit 9 Navitus Record Retention and Record 237</p> <p>Availability Schedule</p> <p>Exhibit 10 Article "The Epidemiology of 267</p> <p>Prescriptions Abandoned at the</p> <p>Pharmacy"</p>	<p style="text-align: right;">Page 9</p> <p>1 P R O C E E D I N G S</p> <p>2 ----</p> <p>3 THE VIDEOGRAPHER: We are now on the</p> <p>4 record. My name is Matt Martin. I'm the</p> <p>5 videographer for Golkow Litigation Services.</p> <p>6 Today's date is February 24, 2022, and the time is</p> <p>7 10:07 a.m. This video deposition is being held in</p> <p>8 Pittsburgh, Pennsylvania for the United States</p> <p>9 District Court, the District of New Jersey,</p> <p>10 MDL No. 2875.</p> <p>11 The deponent is Timothy Kosty.</p> <p>12 Counsel, please identify yourselves for</p> <p>13 the record.</p> <p>14 MR. DORNER: Drew Dornier on behalf of</p> <p>15 the defendants.</p> <p>16 MR. HONIK: Ruben Honik appearing for</p> <p>17 plaintiffs.</p> <p>18 MS. ANDRAS: Tiffany Andras, Greenberg</p> <p>19 Taurig, on behalf of Teva Pharmaceuticals.</p> <p>20 MR. HONIK: Can we ask Ann to just note</p> <p>21 the other appearances so that we don't need to go</p> <p>22 through everybody orally?</p> <p>23 MR. DORNER: We have no objection to</p> <p>24 that.</p> <p>25</p>

Page 10	Page 12
<p>1 MR. HONIK: Drew, you are very faint.</p> <p>2 Are you going to be defending?</p> <p>3 MR. DORNER: Yes. I'll be happy to</p> <p>4 speak up.</p> <p>5 MR. HONIK: Because I could barely hear</p> <p>6 the videographer.</p> <p>7 Ann, we're ready if you want to</p> <p>8 administer the oath.</p> <p>9 TIMOTHY E. KOSTY,</p> <p>10 having been first duly sworn, was examined</p> <p>11 and testified as follows:</p> <p>12 EXAMINATION</p> <p>13 BY MR. HONIK:</p> <p>14 Q. Mr. Kosty, good morning to you.</p> <p>15 A. Good morning.</p> <p>16 Q. My name is Ruben Honik. Can you see and</p> <p>17 hear me?</p> <p>18 A. Yes.</p> <p>19 Q. Great. And just as a housekeeping point</p> <p>20 of order, are you looking at me and the others or</p> <p>21 just me?</p> <p>22 A. I'm looking at you. You're on the</p> <p>23 laptop in front of me. There's a videographer at</p> <p>24 the end of the table. So I might look at that</p> <p>25 camera occasionally, but I'm looking at you.</p>	<p>1 the plaintiffs' lawyers in the case. You may know</p> <p>2 that. And I'm going to start the questioning of</p> <p>3 you today. I anticipate that my colleague,</p> <p>4 Mr. Stanoch, will likewise be examining you. And</p> <p>5 we're likely going to do it in that order. That</p> <p>6 is to say, I'll start. He'll pick up at some</p> <p>7 point. And I may come in on the back end with</p> <p>8 some additional areas of questioning.</p> <p>9 Do you understand that?</p> <p>10 A. Yes.</p> <p>11 Q. So, Mr. Kosty, I'm aware that at the</p> <p>12 least, you've given sworn testimony in legal</p> <p>13 matters in at least two instances, in the Loestrin</p> <p>14 case in which you participated as an expert, and</p> <p>15 in the A&P bankruptcy case; is that right?</p> <p>16 A. That's correct.</p> <p>17 Q. Have you given deposition testimony in</p> <p>18 any other matters at any time before today?</p> <p>19 A. Yes; a couple depositions years ago. I</p> <p>20 don't know how long. At least 15 years. One of</p> <p>21 the cases was a contract dispute with an award on</p> <p>22 the state Medicaid program, and the second dispute</p> <p>23 was another contract dispute between trading</p> <p>24 partners.</p> <p>25 Q. You cut out a little bit when you</p>
Page 11	Page 13
<p>1 Q. And what I'm really getting at is can</p> <p>2 you see the other lawyers as well?</p> <p>3 A. Yes. It's a small conference room.</p> <p>4 Q. Are there lawyers present with you in</p> <p>5 the conference room?</p> <p>6 A. Just the ones who identified themselves,</p> <p>7 yes.</p> <p>8 Q. You're in Pittsburgh; right?</p> <p>9 A. Correct.</p> <p>10 Q. I'm in Philadelphia, and I don't know</p> <p>11 who's in the room with you. Can you tell me who's</p> <p>12 in the room with you?</p> <p>13 A. Yes, the court reporter, the</p> <p>14 videographer, Tiffany Andras and Drew Dorner and</p> <p>15 myself.</p> <p>16 Q. That's all?</p> <p>17 A. Yes.</p> <p>18 Q. Forgive me for not knowing. Are you in</p> <p>19 one of those lawyer's offices or in an office of</p> <p>20 Golkow?</p> <p>21 A. No. We're at the Duane Morris office in</p> <p>22 downtown Pittsburgh.</p> <p>23 Q. In Pittsburgh?</p> <p>24 A. Yeah.</p> <p>25 Q. Okay. With that out of way, I'm one of</p>	<p>1 referred to the Medicaid matter. Can you tell me</p> <p>2 a little bit more about that?</p> <p>3 A. Well, it was actually a state workers'</p> <p>4 comp award to a PBM, and there was a contestation.</p> <p>5 They contested the award. So they asked me to</p> <p>6 testify as an industry expert in that case. So I</p> <p>7 gave --</p> <p>8 Q. Let me -- I apologize. Did you finish?</p> <p>9 I may have spoken over you.</p> <p>10 A. No, I did not. I gave a short expert</p> <p>11 report in that case. And then I testified via</p> <p>12 deposition. I did not testify in court in that</p> <p>13 case. But that was, like I said, 15 years ago. I</p> <p>14 don't keep track of that.</p> <p>15 Q. Okay. But let me unpack what you did a</p> <p>16 little bit. Then we can move on. You represented</p> <p>17 and gave testimony on behalf of the PBM, is that</p> <p>18 what I understood?</p> <p>19 A. One of the workers' comp PBMs, yes.</p> <p>20 Q. And as I understand it, it was a</p> <p>21 workers' comp proceeding in which a worker</p> <p>22 received an award. And you gave some testimony in</p> <p>23 support of one of the PBMs; is that correct?</p> <p>24 A. No, that's not correct.</p> <p>25 Q. All right. Why don't you clarify it for</p>

<p style="text-align: right;">Page 14</p> <p>1 me.</p> <p>2 A. The dispute was over the award of the</p> <p>3 PBM contract to process that state's workers' comp</p> <p>4 claims. So it was many steps above an individual</p> <p>5 patient or workers' comp claimant.</p> <p>6 Q. I understand.</p> <p>7 A. So it was the award to the PBM.</p> <p>8 Q. And have you retained the testimony that</p> <p>9 you gave in that matter?</p> <p>10 A. No. Our document retention policy in</p> <p>11 our company is five years. And every December we</p> <p>12 go through. If it's older than five years, it's</p> <p>13 deleted, destroyed.</p> <p>14 Q. And so given that policy that you've now</p> <p>15 described to me, is it safe to say that your</p> <p>16 company has retained your testimony in the four</p> <p>17 matters that you describe in your report that was</p> <p>18 rendered in this case?</p> <p>19 MR. DORNER: Object to the</p> <p>20 characterization.</p> <p>21 You can answer.</p> <p>22 THE WITNESS: Yes.</p> <p>23 BY MR. HONIK:</p> <p>24 Q. And specifically, for example, did you</p> <p>25 keep your transcript of testimony that you</p>	<p style="text-align: right;">Page 16</p> <p>1 firm's name. I'm trying to remember that. It's</p> <p>2 not coming to the top of my head. Give me a</p> <p>3 minute here, and I'll see if I can remember it.</p> <p>4 BY MR. HONIK:</p> <p>5 Q. While you think about that, Mr. Kosty,</p> <p>6 my next question actually is: What party did you</p> <p>7 give expert testimony on behalf?</p> <p>8 MR. DORNER: Same instruction.</p> <p>9 You can answer.</p> <p>10 THE WITNESS: The defendants.</p> <p>11 BY MR. HONIK:</p> <p>12 Q. And that was what, GSK in that case?</p> <p>13 A. Yes, the maker of Loestrin. I don't</p> <p>14 recall if there were multiple because of all the</p> <p>15 subsidiaries and different manufacturers. I don't</p> <p>16 recall all them, but it was for the defense.</p> <p>17 Q. Right. But suffice to say some law</p> <p>18 firm, the specific name of which you can't</p> <p>19 remember now, on behalf of GSK or one or more of</p> <p>20 its subsidiaries engaged you in that case;</p> <p>21 correct?</p> <p>22 A. That's correct.</p> <p>23 Q. And, similarly, if we go to your firm's</p> <p>24 system, we would be able to locate the</p> <p>25 testimony that you gave in the A&P bankruptcy</p>
<p style="text-align: right;">Page 15</p> <p>1 provided in the Loestrin case?</p> <p>2 A. I am sure it's on our system. I haven't</p> <p>3 looked at it since that case was settled or</p> <p>4 whatever happened to it.</p> <p>5 Q. Right. It was settled. You know that;</p> <p>6 right?</p> <p>7 A. I knew after my testimony. There were</p> <p>8 some other proceedings, but I did not keep up with</p> <p>9 that case to find out what happened at the end.</p> <p>10 But you evidently know it's been settled.</p> <p>11 Q. How long did you work on that case?</p> <p>12 MR. DORNER: Object to form. Vague.</p> <p>13 You can answer.</p> <p>14 THE WITNESS: About four months.</p> <p>15 BY MR. HONIK:</p> <p>16 Q. And who engaged you in that matter?</p> <p>17 A. It was --</p> <p>18 MR. DORNER: While you answer, I'll just</p> <p>19 caution to not answer anything that might be</p> <p>20 subject to a confidentiality or the</p> <p>21 attorney/client privilege.</p> <p>22 But with those instructions, you can</p> <p>23 answer, Mr. Kosty.</p> <p>24 THE WITNESS: It was a law firm. I know</p> <p>25 your next question is going to be what was the law</p>	<p style="text-align: right;">Page 17</p> <p>1 case; correct?</p> <p>2 A. Yes.</p> <p>3 Q. And would we be able to retrieve the</p> <p>4 report or reports, plural, that you prepared in</p> <p>5 each of those cases as well?</p> <p>6 MR. DORNER: And before you answer, I'll</p> <p>7 just note there may be confidentiality</p> <p>8 considerations in either of those cases with</p> <p>9 respect to any testimony or reports given.</p> <p>10 So with that understanding and note on</p> <p>11 the record, you can answer.</p> <p>12 THE WITNESS: I would confer with</p> <p>13 counsel in those cases and get their input before</p> <p>14 disclosing it. I'm not an attorney.</p> <p>15 BY MR. HONIK:</p> <p>16 Q. Right. I haven't asked you --</p> <p>17 MR. DORNER: I'm sorry, Mr. Honik.</p> <p>18 Mr. Honik, the witness was not finished with his</p> <p>19 answer. Could you please let him answer.</p> <p>20 BY MR. HONIK:</p> <p>21 Q. Go ahead, sir. Go ahead, Mr. Kosty.</p> <p>22 A. I would consult with the attorneys in</p> <p>23 that case because there's typically provisions in</p> <p>24 the engagement letter that if any discovery has</p> <p>25 asked for case materials, you have to contact the</p>

<p>Page 18</p> <p>1 attorneys and give them at least an opportunity to 2 object or not. Hold on a second. 3 (There was a discussion off the record.) 4 BY MR. HONIK: 5 Q. Mr. Kosty, let me give you an 6 instruction, and let me go back to the question 7 which you didn't respond to. The instruction is 8 this: Counsel is permitted to lodge objections on 9 the record to protect the record in the interest 10 of our respective clients. There's nothing wrong 11 with that. We're not permitted to make speaking 12 objections which in any way, shape or form 13 suggests an answer to the witness. 14 Now, the question I asked you was not, 15 can you turn the material over to me. It was 16 simply: Does it exist and is it on your system 17 and accessible to you? Can you answer that 18 question? 19 A. Yes, and I previously answered that 20 question. 21 Q. Okay. And as a point of clarification, 22 both your deposition testimony as well as the 23 report or reports that you authored are available 24 to you on your system; is that correct? 25 A. Yes.</p> <p>Page 19</p> <p>1 Q. Now, a couple of words. Inasmuch as 2 you've given testimony before, I won't spend much 3 time on this, but obviously we're not in person, 4 which typically makes this exchange a lot easier. 5 There's sometimes a bit of a lag. And for that 6 reason and others, it's important that only one of 7 us speak at a time. I've already violated that, 8 and I apologize. I will try not to do it again. 9 But let's pledge not to speak over one 10 another so that the court reporter can take down 11 everything that's said in the course of this exam. 12 Can you do that with me? 13 A. Yes. 14 Q. Number two, it's not your job to guess 15 my meaning or to understand the question if you 16 don't understand the question. In fact, I would 17 instruct you if you haven't heard or understood my 18 question, you are not to answer in favor of 19 telling me or asking me to repeat or rephrase it 20 so you do understand it. 21 Will you do that for me? 22 A. Yes. 23 Q. Today is not an endurance test. And so 24 if you need or want to take a break for any reason 25 at any time, just let me know, and we'll take a</p>	<p>Page 20</p> <p>1 break. Okay? 2 A. Yes. 3 Q. Let me give you a little bit of a road 4 map of how I think today will go so there are as 5 few surprises as possible for you. As I 6 mentioned, obviously I've started the examination 7 of you, and as I understand your opinions and 8 reports in this case, I think they can be fairly 9 broken down into two buckets of opinions or 10 information. 11 One pertains to the damages in this case 12 and in particular what Dr. Conti did on behalf of 13 plaintiffs in this case. And the other bucket 14 concerns what we refer to, and I think you might 15 agree, as ascertainability of class membership, 16 which is an area that Laura Craft provided on 17 behalf of plaintiffs and you criticize each of 18 them. Is that fair? 19 MR. DORNER: Object to the 20 characterization. 21 You can answer. 22 THE WITNESS: Yes. 23 BY MR. HONIK: 24 Q. So what I'm going to be doing initially 25 is focusing on the views that you express</p> <p>Page 21</p> <p>1 concerning damages in this case and your 2 criticisms such as it is of Dr. Conti. And 3 Mr. Stanoch, to a great extent, will limit his 4 questions or confine them to Laura Craft's views 5 and in turn your criticism of her. 6 Do you understand that? 7 A. Yes. 8 Q. One or both of us may weave in questions 9 concerning your training, background and 10 experience as it relates to some of the 11 substantive questions that we're going to ask you. 12 And so from time to time, we may interpose areas 13 of question concerning that. 14 Do you understand that? 15 A. Yes. 16 Q. Do you have a written copy of your 17 expert report, dated January 12, 2022, in front of 18 you? 19 A. Yes. I asked counsel to provide me with 20 a clean copy of my report, which they did. 21 Q. And by clean you mean it contains no 22 annotations or notes? 23 A. Correct. 24 Q. Is there a copy in your possession that 25 has notes or annotations?</p>
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<p style="text-align: right;">Page 22</p> <p>1 A. Not in my possession here today, no.</p> <p>2 Q. Okay. And you have a copy, as you</p> <p>3 described it, a clean copy of your expert report</p> <p>4 in front of you?</p> <p>5 A. Yes. It's in a binder here. I'll show</p> <p>6 it to you.</p> <p>7 Q. That's okay. Do you have the three</p> <p>8 appendices that were attached to your expert</p> <p>9 report?</p> <p>10 A. Let me see if I have it included in</p> <p>11 here. Yes, I do. They have included the</p> <p>12 appendices.</p> <p>13 Q. And is it correct, is it not, that you</p> <p>14 prepared and submitted this report, dated</p> <p>15 January 12, 2022; correct?</p> <p>16 A. That is correct.</p> <p>17 Q. Did you prepare the report by yourself?</p> <p>18 A. With assistance from the Analysis Group,</p> <p>19 which is litigation support services that under my</p> <p>20 direction did some of the data analysis for me,</p> <p>21 did some of the background research on citations.</p> <p>22 But it was my report, yes.</p> <p>23 Q. Is it okay if I refer to that outside</p> <p>24 group as AG?</p> <p>25 A. Sure.</p>	<p style="text-align: right;">Page 24</p> <p>1 true, but we need a citation.</p> <p>2 So the Analysis Group helps with</p> <p>3 identifying citations that support my position.</p> <p>4 And then they're also involved with billing for my</p> <p>5 work, and I believe some invoices that they've</p> <p>6 submitted are part of the document disclosure.</p> <p>7 Q. Anything else?</p> <p>8 A. No. That's it.</p> <p>9 Q. I wrote down four things, Mr. Kosty.</p> <p>10 They do data analysis. They do research. They</p> <p>11 provide help in citing or citation. And they do</p> <p>12 billing for your work.</p> <p>13 Did I get that correct?</p> <p>14 A. Yeah. I may have missed a component or</p> <p>15 two, but at the top level, that's the four areas</p> <p>16 that they assist.</p> <p>17 Q. And to be clear, those are the four</p> <p>18 areas in which they assisted you in preparing the</p> <p>19 report in this case; correct?</p> <p>20 A. Yes.</p> <p>21 Q. For the benefit of the record, we're</p> <p>22 going to mark your complete report with the three</p> <p>23 appendices as Kosty Exhibit 1. And I'll refer to</p> <p>24 it as Exhibit 1 from time to time. Is that okay?</p> <p>25 A. Yes.</p>
<p style="text-align: right;">Page 23</p> <p>1 Q. Did AG actually write any of the words</p> <p>2 that comprise your report?</p> <p>3 A. No, they didn't. What they did is they</p> <p>4 provided suggestions, and I was the arbiter of</p> <p>5 those suggestions. Either I thought they were</p> <p>6 appropriate or not. So it was my decision whether</p> <p>7 or not to accept their recommendations. So I</p> <p>8 looked at all suggestions. The report is written</p> <p>9 by me. And that's why I signed it, because it was</p> <p>10 written by me.</p> <p>11 Q. So let me unpack that a little bit. I</p> <p>12 understand that AG does data analysis and you used</p> <p>13 them in that way; is that right?</p> <p>14 A. That's one component of their work, yes.</p> <p>15 Q. And what are the other components to</p> <p>16 which you turned to them for help?</p> <p>17 A. Well, they provide a wide range of</p> <p>18 services. They do data analysis, like I</p> <p>19 mentioned. They also do research into -- it's</p> <p>20 interesting. I don't do a lot of these expert</p> <p>21 reports in our work. My consulting business, you</p> <p>22 know, it's a small component of it. So when you</p> <p>23 have 38 years of experience and you say a</p> <p>24 statement, you know it's true, but oftentimes in</p> <p>25 these legal cases, they say, well, that may be</p>	<p style="text-align: right;">Page 25</p> <p>1 (Kosty Exhibit 1 was marked.)</p> <p>2 BY MR. HONIK:</p> <p>3 Q. You mentioned, and this is how we sort</p> <p>4 of got to this place, you said that they made --</p> <p>5 and I'm paraphrasing you -- recommendations to you</p> <p>6 and you selected those that ultimately were</p> <p>7 incorporated in your report.</p> <p>8 Did I get that right?</p> <p>9 MR. DORNER: Object to the</p> <p>10 characterization.</p> <p>11 You can answer.</p> <p>12 THE WITNESS: Yes.</p> <p>13 BY MR. HONIK:</p> <p>14 Q. When you say they made recommendations</p> <p>15 to you, what kinds of recommendations did they</p> <p>16 make?</p> <p>17 A. It was mainly on background information</p> <p>18 on the deals, the details associated with it.</p> <p>19 Q. And when you say background, what do you</p> <p>20 mean by background?</p> <p>21 A. Well, one example I can cite is the</p> <p>22 Medicaid Part D financial structure. It's been</p> <p>23 the same structure since the program was</p> <p>24 implemented in 2006. The details have changed in</p> <p>25 terms of what components are paid, what are the</p>

<p style="text-align: right;">Page 26</p> <p>1 risk corridors, what is the deductible levels each 2 year. 3 So in order to make sure that it was up 4 to date for this report, they would do the 5 research into the components that now are 6 applicable for that Part D program. And they 7 change every year based on CMS's call letter and 8 what changes are made to the program in terms of 9 the financing. So that's one example of how they 10 did the detailed research to say, all right, the 11 Med D program has all these four components. 12 However, this is what it looks like today based 13 upon their review of a call letter from CMS. 14 Q. Mr. Kosty, the example that you gave me, 15 which you describe as background that resulted 16 from detailed research, that's an example of a 17 recommendation that AG made to you? 18 A. Yes. 19 Q. And if I understood your previous 20 testimony, there were certain recommendations that 21 you accepted and incorporated into your report and 22 others that you didn't; is that correct? 23 A. That is correct. 24 Q. Can you give me an example of something 25 that they recommended that you declined to put in</p>	<p style="text-align: right;">Page 28</p> <p>1 Beckford. Those three individuals were my primary 2 contacts. 3 So I would instruct them on what I was 4 looking for, and then it was up to them to decide 5 how to utilize the resources within their company 6 to comply with my request. So if they -- 7 Q. Let's say -- 8 MR. DORNER: I'm sorry. Mr. Kosty 9 wasn't finished. 10 THE WITNESS: So if there was analyst 11 work that needed to be done, I don't micromanage 12 how they do their work. It's up to them to 13 decide. Here's what I need. How they go about 14 doing that and coming back to me, it's not up to 15 me to decide or direct. 16 BY MR. HONIK: 17 Q. You mentioned a moment ago that these 18 are the folks with whom you interfaced to make 19 requests; correct? 20 A. Requests for data analysis, requests for 21 research, those four areas. 22 Q. And when you would make those requests, 23 would you make them in writing, that is, would you 24 convey your request by email or letter? How would 25 you do that?</p>
<p style="text-align: right;">Page 27</p> <p>1 your report? 2 MR. DORNER: Objection. And I'll just 3 instruct you not to divulge the contents of any 4 draft reports or forms of draft reports that you 5 may have prepared. 6 With that, if you're able to answer, you 7 can answer. 8 THE WITNESS: None comes to mind. I 9 know there was plenty because based on my 10 experience in the industry, if you're not in the 11 industry, you might read something and come to a 12 conclusion that's inaccurate. So I would review 13 what was proposed and say, no, that doesn't -- 14 that's not how it works. It's the wrong citation. 15 It's the wrong research. 16 So I don't have a specific instance I 17 can cite for you right now, but that's the process 18 that we went through. 19 BY MR. HONIK: 20 Q. And with whom did you interface at AG 21 regarding receipt of these recommendations? Who 22 did you speak with or communicate with? 23 A. My interface at AG is Brian Ellman, who 24 is the vice president there, one of the vice 25 presidents; Ngoc Pham, who is a manager, and Tom</p>	<p style="text-align: right;">Page 29</p> <p>1 A. It would be either via email or 2 telephone call. 3 Q. And would it be fair to say that all of 4 the email exchanges you had with these individuals 5 at AG requesting assistance are emails that are on 6 your system? 7 A. The ones that I kept were, but I don't 8 keep all my emails. I get hundreds of emails a 9 day. So the ones that are pertinent, I may have 10 kept. Others I delete immediately. If you're on 11 an email string and you have eight emails on the 12 same damn subject, I don't keep eight emails. If 13 it's an important issue, I might keep the last 14 email, but not all eight of them. It's just not 15 practical. 16 Q. Is there a document that reflects the 17 retention of AG to provide assistance to you? 18 A. There's an engagement letter between AG 19 and the defendants, defendants' counsel, to engage 20 me. So I don't have a direct engagement letter 21 with the defendants' counsel. I'll work -- my 22 billing is through AG. They handle the billing 23 for me. 24 Q. So is it my understanding that AG 25 brought you into this case?</p>

<p style="text-align: right;">Page 30</p> <p>1 MR. DORNER: Object to the 2 characterization. 3 You can answer. 4 THE WITNESS: My understanding of it is 5 counsel approached AG and said, do you know an 6 expert with these qualifications. And AG said, 7 well, we have worked with Mr. Kosty before. We'll 8 set up a phone call and you can talk to him and 9 decide if he meets the needs of this case or not. 10 BY MR. HONIK: 11 Q. And then who did you speak with? 12 A. Can you be more specific? Speak with 13 who, from what company? 14 Q. What counsel did you speak with to see 15 if there was a match? 16 MR. DORNER: And again I'll caution not 17 to get into the subject of any conversations. 18 But you can answer. 19 THE WITNESS: I don't recall 20 specifically. There's many counsel and defendants 21 on this case. I believe on one call there was 15 22 counsel. I don't recall who those people were. 23 BY MR. HONIK: 24 Q. Right. So what you did, Mr. Kosty, you 25 explained to me how you got involved. You've told</p>	<p style="text-align: right;">Page 32</p> <p>1 product of counsel. 2 BY MR. HONIK: 3 Q. What characteristics or background and 4 training and experience did you identify in that 5 initial meeting to counsel? 6 MR. DORNER: Same objection. Same 7 instruction. 8 BY MR. HONIK: 9 Q. That you possessed. 10 MR. DORNER: Same instruction. 11 THE WITNESS: On the advice of 12 counsel -- 13 MR. HONIK: You're instructing him not 14 to answer what he said? 15 MR. DORNER: It reflects the work 16 product of counsel because he's answering our 17 questions. Yes, I am. Please move on. 18 BY MR. HONIK: 19 Q. When you were hired, Mr. Kosty, did you 20 execute or have counsel send a letter reflecting 21 your retention? 22 A. Not directly from me. AG has an 23 engagement letter with counsel. 24 Q. Okay. Does AG have an engagement letter 25 with you?</p>
<p style="text-align: right;">Page 31</p> <p>1 me that AG has a retention or engagement letter or 2 arrangement with defense counsel, and that defense 3 counsel sought an expert with certain 4 qualifications and that's how you got involved. 5 Did I get that straight? 6 A. Yes. 7 Q. And my initial question before I move 8 forward is: In that initial contact, can you 9 identify by name any of the attorneys who, I'll 10 say, interviewed you to see if there was a fit? 11 A. I think Drew Dorner is the only attorney 12 I remember who was the call because he's continued 13 after I've been engaged as one of the primary 14 defense counsel. 15 Q. Okay. Now, with respect to the 16 background or characteristics that you said they 17 were looking for, what characteristics or areas of 18 expertise were they looking for? 19 A. I don't know. They didn't share it with 20 me. 21 Q. Well, when Mr. Dorner and perhaps others 22 interviewed you to see if you were suitable, what 23 were they looking for? 24 MR. DORNER: Objection. I'll instruct 25 you not to answer. That gets into the work</p>	<p style="text-align: right;">Page 33</p> <p>1 A. No. 2 Q. And is there one or more communications, 3 be it email or otherwise, that reflects your 4 engagement or retention in the case with anyone? 5 A. There would be an email from the 6 Analysis Group that would have indicated to me 7 that we've been retained, I've been retained 8 through Analysis Group on this case. Whether I 9 kept that email or not, I don't recall. But I 10 could certainly look if needed. 11 Q. Okay. But you remember getting such an 12 email; right? 13 A. Yes. 14 Q. And that came from the AG group you to; 15 right? 16 A. Yes. 17 Q. And did that email describe what you 18 were tasked to do? 19 A. At a very high level, yes. 20 Q. Can you tell me what you were asked to 21 do that's reflected in that email? 22 A. Provide expert insight, consulting, 23 perhaps an expert report and testimony. When I 24 was engaged, it was unclear exactly what my role 25 was going to be. So it was a vague description,</p>

<p style="text-align: right;">Page 34</p> <p>1 high level like I mentioned.</p> <p>2 Q. Did it become clearer as time went on?</p> <p>3 A. Absolutely.</p> <p>4 Q. And what specific clarification did you</p> <p>5 receive regarding your assignment as time went on?</p> <p>6 MR. DORNER: Objection. Lack of</p> <p>7 foundation.</p> <p>8 You can answer.</p> <p>9 THE WITNESS: The instruction I got was</p> <p>10 I needed to produce an expert report evaluating</p> <p>11 Ms. Craft, Dr. Conti's and Dr. Panagos' opinions</p> <p>12 of the case and then provide the court background</p> <p>13 on the industry and how it works based on my 38</p> <p>14 years of experience.</p> <p>15 BY MR. HONIK:</p> <p>16 Q. Okay. And we may go into this a little</p> <p>17 more as the deposition goes on today, Mr. Kosty,</p> <p>18 but you're a pharmacist with an MBA; right?</p> <p>19 A. That's correct, yes.</p> <p>20 Q. And as I know it from your CV, you were</p> <p>21 for roughly 12 or 13 years working for Rite-Aid</p> <p>22 and then Thrift Drug as a pharmacist on the</p> <p>23 business side; correct?</p> <p>24 A. Yes. In my career, I started dispensing</p> <p>25 prescriptions for about a year and a half at a</p>	<p style="text-align: right;">Page 36</p> <p>1 our senior executive management wanted us to own</p> <p>2 the means of production.</p> <p>3 So I got to put all that together and</p> <p>4 hire people then to help me run it. And then my</p> <p>5 job after we stood up the company was to help</p> <p>6 create differentiating services so we could sell</p> <p>7 in the marketplace our services.</p> <p>8 Q. And it was sold; was it not?</p> <p>9 A. Well, we left the company in '96 to</p> <p>10 start our consulting company. Thrift Drug -- it's</p> <p>11 a long story, but Thrift Drug was merged with</p> <p>12 Eckerd Health Services. J.C. Penney's owned</p> <p>13 Thrift Drug. And they decided to let -- after we</p> <p>14 had left, the Eckerd Health Services people kind</p> <p>15 of ran the PBM. And then it was rolled up through</p> <p>16 acquisitions, through PharmaCare and eventually in</p> <p>17 CVS Caremark.</p> <p>18 Q. And I gather, Mr. Kosty, your experience</p> <p>19 in helping start that business coupled with your</p> <p>20 background as a pharmacist is what catapulted you</p> <p>21 into the consulting side; correct?</p> <p>22 A. Yes. When we left and started our</p> <p>23 business, the genesis of it was we see a lot of,</p> <p>24 and we still do today, silos in the industry where</p> <p>25 people in certain market segments understand</p>
<p style="text-align: right;">Page 35</p> <p>1 pharmacy in Whitesville, West Virginia. Shortly</p> <p>2 thereafter, I was promoted into a district manager</p> <p>3 role where I managed 25 pharmacies. That was more</p> <p>4 beginning the business side of it.</p> <p>5 And then subsequent, I managed the</p> <p>6 third-party operations at both companies, Rite-Aid</p> <p>7 for about five years and Thrift Drug for about a</p> <p>8 year.</p> <p>9 Q. Right. And toward the end of your</p> <p>10 tenure at Thrift Drug, you were involved in the</p> <p>11 creation of a PBM that was created by Thrift;</p> <p>12 right?</p> <p>13 A. Yes. I was lucky to be the second</p> <p>14 employee hired for that new business, and the CEO</p> <p>15 told me -- tasked me with the opportunity to build</p> <p>16 a company which not many times in your career you</p> <p>17 have that opportunity. So I ran with it.</p> <p>18 My job was to build all the</p> <p>19 administrative functions of the PBM and hire</p> <p>20 people to run those functions. So it included</p> <p>21 developing a clinical component, clinical</p> <p>22 services. We stood up a call center for both</p> <p>23 pharmacies and patients to call. We had network</p> <p>24 administration. We did an RFP and installed a</p> <p>25 multimillion dollar claims processing system that</p>	<p style="text-align: right;">Page 37</p> <p>1 certain things, but they don't have the</p> <p>2 perspective of the multiple market segments.</p> <p>3 So when I say market segments, I mean</p> <p>4 manufacturers, branded and generic companies.</p> <p>5 Then you have the payor segment where you have</p> <p>6 PBMs. You could have health plans, workers' comp</p> <p>7 PBMs, Medicaid Part D plans, a number of different</p> <p>8 payor types.</p> <p>9 Then you have pharmacies where you have</p> <p>10 retail pharmacy chains. That was my background.</p> <p>11 Initially you have specialty pharmacies. You have</p> <p>12 mail service pharmacies. You have different types</p> <p>13 of pharmacies we consult with. And then we also</p> <p>14 worked with technology companies that help</p> <p>15 businesses within the pharmaceutical market become</p> <p>16 more efficient and profitable. And we also work</p> <p>17 we say an et al. category, which would include our</p> <p>18 legal work.</p> <p>19 Q. Okay. How much of the work that your</p> <p>20 company presently does is legal versus support for</p> <p>21 the pharma or tech side of the business?</p> <p>22 MR. DORNER: Objection. Vague.</p> <p>23 You can answer.</p> <p>24 THE WITNESS: Our legal work is very</p> <p>25 minimal for our company. It's under -- I'd</p>

<p style="text-align: right;">Page 38</p> <p>1 estimate 15 percent or under. Quite frankly, we 2 enjoy working with clients on real business 3 issues. We've obtained a lot of expertise working 4 on different business issues and understanding 5 different segments. That's a lot of fun. 6 I'm not sure if I'd characterize this as 7 fun, but it's part of the legal process, right. 8 So it's not a big component of our consulting 9 business. 10 BY MR. HONIK: 11 Q. So when you say 15 percent or less, do 12 you mean by revenue or time spent? 13 A. Revenue. 14 Q. How would you quantify it in terms of 15 time spent? 16 A. Well, in the last couple of months, it's 17 been a lot of time spent. But typically I will 18 work on five to ten different client engagements 19 at a time, and that keeps me busy a hundred 20 percent of the time. 21 Q. How many folks work in your firm? 22 A. We have 15 full-time employees. We have 23 eight pharmacists on staff. We have an MBA from 24 the University of Chicago joined us last year. 25 Q. I'm sorry. What? I didn't hear.</p>	<p style="text-align: right;">Page 40</p> <p>1 economics, do you? 2 A. I don't have any degrees in economics, 3 no. 4 Q. You know, do you not, that there's a 5 specialty area within economics as an academic 6 pursuit called health economics; correct? 7 A. Yes. 8 Q. And you're not a health economics expert 9 either, are you? 10 MR. DORNER: Object to form. 11 You can answer. 12 THE WITNESS: Maybe. It depends how you 13 define an expert. I certainly know the economic 14 background on how things work in the economy, and 15 I can read and understand people's opinions on 16 different components. So I don't need to be an 17 economist or a healthcare economist to do that. 18 BY MR. HONIK: 19 Q. Suffice to say you've made no 20 contributions to the academic peer-reviewed 21 literature in economics? 22 A. Suffice it to say that's correct. 23 Q. You've never taught a course at any 24 level, undergraduate or graduate, in economics or 25 health economics; correct?</p>
<p style="text-align: right;">Page 39</p> <p>1 A. I'm sorry. MBA, business-type person 2 who joined us, some great experience. Then we 3 have IT, a couple IT people. We have 4 administrative assistant support that is about 60 5 or 40 percent of our employee base helps us, 6 allows our consultants to focus on projects and 7 not worry about the administrative work. 8 Q. Do you have any economists on your 9 staff? 10 A. No. 11 Q. And you, yourself, don't hold yourself 12 out to be an economist, do you? 13 A. I haven't been trained as an economist, 14 but in my coursework both at Ohio State and 15 graduate work at Penn State to get my MBA, I've 16 had a number of economic courses, yes. 17 Q. But you understand that there's such a 18 thing as a professional economist who is trained 19 to serve in that capacity; right? 20 MR. DORNER: Object to the 21 characterization. 22 You can answer. 23 THE WITNESS: Yes. 24 BY MR. HONIK: 25 Q. And you don't have any degrees in</p>	<p style="text-align: right;">Page 41</p> <p>1 A. Correct. 2 Q. We'll get back to some of your 3 qualifications and experience, but I just wanted 4 to establish that. 5 Is there anyone at AG upon whom you 6 relied as an economist in doing the work in this 7 case? 8 MR. DORNER: Object to the form. Vague. 9 You can answer if you can. 10 THE WITNESS: One of the persons who 11 worked on the case was an economist, but he wasn't 12 working for me in that role. It was more of an 13 analyst role for data. 14 BY MR. HONIK: 15 Q. And who was that? 16 A. Tom Beckford. 17 Q. You said Tom Beckford? 18 A. Correct. 19 Q. So Mr. Beckford is an economist, but 20 didn't work for you in this case or on this case 21 in that capacity, is that what you mean? 22 A. Yes. 23 Q. And was he the only economist at AG with 24 whom you were involved? 25 MR. DORNER: Object to foundation.</p>

<p style="text-align: right;">Page 42</p> <p>1 You can answer.</p> <p>2 THE WITNESS: He was the only economist</p> <p>3 I was involved with or worked with me on my</p> <p>4 report. I don't know if they have other</p> <p>5 economists. I assume they do, but I haven't met</p> <p>6 them.</p> <p>7 BY MR. HONIK:</p> <p>8 Q. So limiting my area of questioning and</p> <p>9 interest to folks that helped you in this case to</p> <p>10 write your report, the only one would be Tom</p> <p>11 Beckford, and he didn't work with you in his</p> <p>12 capacity as an economist. Did I get that right?</p> <p>13 A. Yes.</p> <p>14 Q. What did he do if not serve as an</p> <p>15 economist to support you? What did he do?</p> <p>16 A. Data analysis.</p> <p>17 Q. I'm sorry. You said data analysis?</p> <p>18 A. Yes.</p> <p>19 Q. And can you be a little more particular</p> <p>20 and tell me what kind of data analysis he did on</p> <p>21 your behalf in support of your work in this case?</p> <p>22 A. Sure. Let me give you an example from</p> <p>23 my report. If you go to Table 1. That's the</p> <p>24 problem with writing a long report. There's a lot</p> <p>25 of pages to go through.</p>	<p style="text-align: right;">Page 44</p> <p>1 answer negative, "no"?</p> <p>2 BY MR. HONIK:</p> <p>3 Q. Did you say "no," sir?</p> <p>4 A. That's correct.</p> <p>5 Q. Can you tell me why you didn't speak to</p> <p>6 Mr. Beckford about the economic theories that</p> <p>7 underpin Dr. Conti's views?</p> <p>8 MR. DORNER: Same objection.</p> <p>9 You can answer.</p> <p>10 THE WITNESS: I didn't need his opinion.</p> <p>11 BY MR. HONIK:</p> <p>12 Q. Did you, nonetheless, ask him his</p> <p>13 opinions?</p> <p>14 A. No.</p> <p>15 Q. Okay. Did he offer any insights as you</p> <p>16 suggested to me at the beginning of your sworn</p> <p>17 testimony that you rejected, recommendations from</p> <p>18 Beckford that you declined to incorporate in your</p> <p>19 report or analysis?</p> <p>20 MR. DORNER: Objection. Asked and</p> <p>21 answered.</p> <p>22 You can answer.</p> <p>23 THE WITNESS: I don't recall specifics,</p> <p>24 no.</p> <p>25</p>
<p style="text-align: right;">Page 43</p> <p>1 Q. What page are you on?</p> <p>2 A. I'm not there yet.</p> <p>3 (There was a discussion off the record.)</p> <p>4 BY MR. HONIK:</p> <p>5 Q. Are you at a page yet, Mr. Kosty?</p> <p>6 A. No. It's Table 1. I'm sorry. I don't</p> <p>7 have this memorized what page it's on.</p> <p>8 Q. Take a look at page 27. It might be</p> <p>9 there.</p> <p>10 A. Thank you. Yes. So an example, to</p> <p>11 create Table 1, we took IQVIA data, added the</p> <p>12 method of payment to that data, and then sorted</p> <p>13 differently by method of payment to create this</p> <p>14 table. So that's one example of how Tom Beckford</p> <p>15 helped with the data analysis of this report.</p> <p>16 Q. So Mr. Beckford, the economist at AG,</p> <p>17 helped to prepare Table 1. That's an example?</p> <p>18 A. Yes.</p> <p>19 Q. Did you discuss with Mr. Beckford any of</p> <p>20 the economic theories Dr. Conti speaks of in her</p> <p>21 report to get his insights?</p> <p>22 A. No.</p> <p>23 MR. DORNER: Objection. Vague. The</p> <p>24 question is answered. That's fine.</p> <p>25 MR. HONIK: Did the reporter get the</p>	<p style="text-align: right;">Page 45</p> <p>1 BY MR. HONIK:</p> <p>2 Q. Can you give me a single example of a</p> <p>3 recommendation anyone at AG made in connection</p> <p>4 with your work in this case that you rejected?</p> <p>5 MR. DORNER: Objection. Asked and</p> <p>6 answered.</p> <p>7 You can answer.</p> <p>8 THE WITNESS: I previously responded no.</p> <p>9 I don't recall offhand.</p> <p>10 BY MR. HONIK:</p> <p>11 Q. Okay. You gave me a single example of a</p> <p>12 recommendation that you accepted. Do you know of</p> <p>13 any others that you can recall today?</p> <p>14 A. No. I can't recall specifics.</p> <p>15 Q. You've given me this example of Table 1</p> <p>16 as something that Mr. Beckford assisted you in.</p> <p>17 And I had asked you earlier what parts of this</p> <p>18 report, the actual language, tables and other</p> <p>19 material that we find here, was authored by AG</p> <p>20 versus you.</p> <p>21 Can you tell me any other places that AG</p> <p>22 wrote in this report, Exhibit 1?</p> <p>23 MR. DORNER: Object to the</p> <p>24 characterization.</p> <p>25 You may answer.</p>

<p style="text-align: right;">Page 46</p> <p>1 THE WITNESS: You mischaracterized my 2 statement around Table 1. I asked them to produce 3 it for me to evaluate it. I went through their 4 methodology. I checked it myself. And then I 5 agreed to put it in my report. 6 BY MR. HONIK: 7 Q. Understood. Are there any other parts 8 of your written report marked Exhibit 1 that was 9 authored in whole or in part by anyone at AG? 10 MR. DORNER: Objection. 11 BY MR. HONIK: 12 Q. You can answer. 13 MR. DORNER: You can answer. I'll 14 object to form, but you can answer. 15 THE WITNESS: They assisted with the 16 tables that were created for this report. 17 BY MR. HONIK: 18 Q. Understood. Is there any other language 19 that AG wrote that's in Exhibit 1? 20 MR. DORNER: Object to form. 21 Mischaracterization. Asked and answered. 22 You can answer. 23 THE WITNESS: As I previously testified, 24 they made suggestions. It was up to me to 25 evaluate suggestions. But when I accepted them, I</p>	<p style="text-align: right;">Page 48</p> <p>1 they made comments to those drafts or to that 2 draft, some of which you accepted, others that you 3 rejected, and then you incorporated them in a new 4 draft? Is that part of the way you did this? 5 MR. DORNER: Object to form. Compound. 6 You may answer. 7 THE WITNESS: Yes. Certainly in 8 drafting and creating a hundred-page report, you 9 don't just sit down and write the final copy to 10 start with. 11 BY MR. HONIK: 12 Q. Absolutely. Absolutely. 13 A. If someone can do that, I'd love to meet 14 them. But you have to go through, create, 15 criticize, edit, update and repeat. 16 Q. Understood. 17 A. I don't know any other expert that would 18 sit down and write an entire report. So that's 19 the process we went through. I would create the 20 report. I would get feedback. I would edit my 21 report. And then there would be another iteration 22 until we got to the final product. 23 BY MR. HONIK: 24 Q. Totally understand. How many different 25 iterations would you say you exchanged with AG</p>
<p style="text-align: right;">Page 47</p> <p>1 accepted them into my report. 2 BY MR. HONIK: 3 Q. I totally understand that, Mr. Kosty. 4 I've moved past that. And I'm asking a very 5 specific question. You, yourself, identified 6 correctly that this is a long report with many 7 sections. 8 I'm asking you whether there is any 9 language or other material in this report that was 10 specifically authored, written by anyone at AG. 11 Yes or no. 12 MR. DORNER: Object to form. 13 Mischaracterization. Asked and answered. The 14 witness is also permitted to offer an explanation. 15 He can't be forced to answer "yes" or "no." 16 With that, you can answer one more time. 17 THE WITNESS: As I said twice before, 18 they made suggestions. I evaluated suggestions, 19 and I decided what to include or not. 20 BY MR. HONIK: 21 Q. Let me understand how this suggestion 22 and recommendation process worked. Did you write 23 a draft of the report and then share it with AG? 24 A. Yes. 25 Q. And did you undergo a process in which</p>	<p style="text-align: right;">Page 49</p> <p>1 before the final form of this report as submitted 2 to plaintiffs' counsel occurred? 3 A. I have no idea. 4 Q. Well, more than five? 5 MR. DORNER: Objection. Asked and 6 answered. 7 You can answer. 8 THE WITNESS: It was more than five. 9 The exact number I don't know. 10 BY MR. HONIK: 11 Q. And over what period of time would this 12 iterative exchange of drafts and comments -- how 13 long did it take place? 14 A. I'm trying to recall. I was engaged on 15 the project I think in early August. So it was 16 probably somewhere in the October, November 17 timeframe I started working on a report. But I 18 don't recall the specific date. I don't know if 19 it's October 31, it's November 1, but it was about 20 that timeframe. 21 Q. And what areas of your report did you 22 solicit comments from AG on? 23 A. I solicited comments on the entire 24 report. 25 Q. Did you solicit comments from AG as to</p>

<p style="text-align: right;">Page 50</p> <p>1 the specifics of the opinions authored by 2 Dr. Conti? 3 MR. DORNER: Objection. Vague. And 4 form. 5 But you can answer. 6 THE WITNESS: No. 7 BY MR. HONIK: 8 Q. Did you send Dr. Conti's report up to 9 the folks at AG? 10 A. I believe they have access to the 11 report. I didn't send it to them. Perhaps 12 defense counsel sent it to them. 13 Q. Did you discuss Dr. Conti's reports with 14 the folks at AG? 15 A. Yes. 16 Q. Did you discuss Laura Craft's report 17 with the folks at AG? 18 A. Yes. 19 Q. And did they offer comments first as to 20 Rena Conti's opinions to you? 21 A. Based on my report, they offered me 22 comments. I mean, obviously, when you review 23 someone's report, you'll have a discussion on the 24 contents, et cetera. That's just a normal course 25 of business.</p>	<p style="text-align: right;">Page 52</p> <p>1 BY MR. HONIK: 2 Q. And one or more folks at AG provided 3 recommendations, substantive recommendations about 4 the section of your report that pertains to 5 Dr. Conti; is that correct? 6 MR. DORNER: Object to form. 7 Characterization. 8 You may answer. 9 THE WITNESS: Your word is substantial 10 or substantive I believe you said, counselor. I 11 don't recall if they were or were not. But like I 12 indicated earlier, I had requested feedback on the 13 entirety of my report. So whatever feedback they 14 provided, as I mentioned three times previously, I 15 reviewed and decided whether it had merit or not 16 and either included or did not. 17 BY MR. HONIK: 18 Q. So I'm still trying to understand the 19 process. And the reason for that, Mr. Kosty, is 20 that the court in this case, in the valsartan case 21 is going to need to understand your methodology 22 about how you arrived at your opinions. 23 Do you understand that? 24 MR. DORNER: Object to form. Calls for 25 a legal conclusion.</p>
<p style="text-align: right;">Page 51</p> <p>1 Q. Well, that's what I'm trying to unpack 2 and understand before we move on, Mr. Kosty. With 3 respect specifically to Dr. Conti's report, you 4 first and foremost spoke with AG about her 5 opinions; is that correct? 6 MR. DORNER: Object to the 7 characterization. 8 You may answer. 9 THE WITNESS: I wouldn't say first and 10 foremost. That's not my words. They were a 11 component of the discussion. Obviously, there was 12 discussion with counsel about it, too. 13 BY MR. HONIK: 14 Q. Mr. Kosty, I apologize. I don't think I 15 made myself clear. I don't mean first and 16 foremost on your part. I mean that's the first 17 question I have that's foundational. And all I'm 18 trying to establish at the outset, and I'll ask 19 more questions as we go along, you spoke to one or 20 more people at AG about Dr. Conti's opinions in 21 this case; correct? 22 MR. DORNER: Objection. Asked and 23 answered. 24 You may answer. 25 THE WITNESS: Yes.</p>	<p style="text-align: right;">Page 53</p> <p>1 But you may answer. 2 THE WITNESS: Yes. 3 BY MR. HONIK: 4 Q. And part of your methodology was to rely 5 upon advice from AG in the preparation of your 6 report; was it not? 7 MR. DORNER: Object to the 8 characterization. 9 You may answer. 10 THE WITNESS: I did not rely on AG to 11 write my report is what you're asking. It's my 12 report. 13 BY MR. HONIK: 14 Q. No, sir. That's not what I'm asking. 15 MR. DORNER: I'm sorry. The witness 16 wasn't finished with his answer. Go ahead, 17 Mr. Kosty. 18 THE WITNESS: Thank you. 19 In Dr. Conti's section, I read her 20 expert report and came to my own conclusions. 21 Those directed my writing and my report in that 22 section that I criticized her methodology. Those 23 are my conclusions based on my reading of the 24 facts in the case. 25</p>

<p style="text-align: right;">Page 54</p> <p>1 BY MR. HONIK:</p> <p>2 Q. Mr. Kosty, I have no doubt that you</p> <p>3 arrived at your own impressions about Dr. Conti's</p> <p>4 views and that you wrote the section that</p> <p>5 criticizes her. I have no doubt about that.</p> <p>6 But you've also confirmed to me that you</p> <p>7 spoke with one or more persons at AG about</p> <p>8 Dr. Conti's opinions and views; isn't that</p> <p>9 correct?</p> <p>10 A. Yes.</p> <p>11 Q. So first question based on that</p> <p>12 foundational point is: Who did you speak with</p> <p>13 about Dr. Conti's views at AG?</p> <p>14 A. It would be Brian Ellman, Ngoc Pham and</p> <p>15 Tom Beckford, and there was one other person who</p> <p>16 has since left their company, Kelly Adamski.</p> <p>17 Q. Kelly?</p> <p>18 A. Adamski.</p> <p>19 Q. Where is Ms. Adamski now?</p> <p>20 A. I have no idea.</p> <p>21 MR. DORNER: Object to form. Calls for</p> <p>22 speculation.</p> <p>23 You can answer if you can.</p> <p>24 THE WITNESS: I don't know.</p> <p>25</p>	<p style="text-align: right;">Page 56</p> <p>1 Mr. Kosty is to not divulge the contents of any</p> <p>2 draft of a report. It's a simple instruction.</p> <p>3 Clearly not improper, Mr. Honik. It's in the</p> <p>4 federal rules.</p> <p>5 And with that instruction and an</p> <p>6 objection to the form, you may answer.</p> <p>7 THE WITNESS: I don't recall specifics.</p> <p>8 BY MR. HONIK:</p> <p>9 Q. What topics did you discuss with those</p> <p>10 four people concerning Dr. Conti's views?</p> <p>11 A. Like I said, I don't recall specifics of</p> <p>12 those discussions, but obviously we would have had</p> <p>13 to discuss the methodology and her conclusions.</p> <p>14 Q. So you've now identified that you</p> <p>15 discussed the methodology that Dr. Conti used; is</p> <p>16 that right?</p> <p>17 A. Yes.</p> <p>18 Q. What was that discussion? What did you</p> <p>19 and the four people at AG discuss concerning</p> <p>20 Dr. Conti's methodology?</p> <p>21 MR. DORNER: Same instruction with</p> <p>22 respect to drafts.</p> <p>23 But you may otherwise answer.</p> <p>24 THE WITNESS: I don't recall that</p> <p>25 specific discussion.</p>
<p style="text-align: right;">Page 55</p> <p>1 BY MR. HONIK:</p> <p>2 Q. What did you speak to these four people</p> <p>3 about at AG as concerns Dr. Conti's opinions and</p> <p>4 views?</p> <p>5 MR. DORNER: I'll caution not to get</p> <p>6 into any discussions particularly where counsel</p> <p>7 were involved and also which would be reflected in</p> <p>8 drafts of your report which are work product.</p> <p>9 MR. HONIK: That's an improper</p> <p>10 instruction, Mr. Doren.</p> <p>11 MR. DORNER: You can put that on the</p> <p>12 record, Mr. Honik, but draft reports you're not</p> <p>13 accessible to.</p> <p>14 With that, to the extent you can answer,</p> <p>15 you may answer.</p> <p>16 BY MR. HONIK:</p> <p>17 Q. Before you do, Mr. Kosty, I've not asked</p> <p>18 you a single question about the drafts. What I've</p> <p>19 asked you, for clarification, and Mr. Dorners</p> <p>20 instructions are highly improper in shaping your</p> <p>21 testimony, is simply: What did you discuss with</p> <p>22 the four people at AG that you've now identified</p> <p>23 to me as it concerns Dr. Conti's views and</p> <p>24 impressions in her report?</p> <p>25 MR. DORNER: And the instruction to</p>	<p style="text-align: right;">Page 57</p> <p>1 BY MR. HONIK:</p> <p>2 Q. How is it you recall that you discussed</p> <p>3 methodology that Dr. Conti employed?</p> <p>4 A. Well, if you read the report, you have</p> <p>5 to read the methodology, right. And you also have</p> <p>6 to look at the conclusion based on those</p> <p>7 methodologies, which I say in my report, and I'm</p> <p>8 sure we'll get into later, I disagree with</p> <p>9 completely. But it's my reading of the report, my</p> <p>10 analysis and recommendations of critique of her</p> <p>11 work is in my report.</p> <p>12 Q. Okay. So let me unpack that. You</p> <p>13 discuss and write about the methodology Dr. Conti</p> <p>14 employed, and you're assuming you spoke to these</p> <p>15 four people about that. Is that what you're</p> <p>16 telling me?</p> <p>17 MR. DORNER: Object to the</p> <p>18 characterization.</p> <p>19 You may answer, Mr. Kosty.</p> <p>20 THE WITNESS: This mischaracterizes the</p> <p>21 statement. We may have discussed the methodology</p> <p>22 and her conclusion, but in the report, when I came</p> <p>23 to my conclusion, which is in my report that her</p> <p>24 methodology -- she creates an alternative reality</p> <p>25 of how the world works, and she defends that</p>

<p>Page 58</p> <p>1 reality that nowhere shall I go outside of that 2 alternative reality. And if you question my 3 alternative reality, you're wrong. 4 Well, in the real world, things work 5 differently, Mr. Honik. People have to go to the 6 pharmacy. They need to be treated for their 7 medication -- their healthcare issues. In this 8 case, the products were in the marketplace. They 9 were dispensed to millions of patients, right, and 10 they were effective in treating people's blood 11 pressures and preventing adverse outcomes. 12 So along that way, people got tremendous 13 therapeutic value from these products. So to say 14 they're worthless is just nonsense. Those 15 products stayed out of the hospital. They didn't 16 have strokes. They didn't have heart attacks. 17 They kept them healthy. Even in the 18 economic plaintiffs, people that were deposed 19 said, yeah, we received benefit from these 20 products. 21 So when Dr. Conti says they're 22 worthless, that just does not hold any water in 23 how the real world works. Unfortunately, things 24 happen and you have to deal with it, and that's 25 what was done in this case when the manufacturer</p> <p>Page 59</p> <p>1 identified there was an impurity. They didn't 2 know what the impurity was. They did some 3 research and they went to the FDA. The FDA 4 conducted the research in 2018. And you can look 5 on their website for the entire chronology of what 6 happened. 7 Then they decided to implement voluntary 8 recalls. And part of the recall notices to 9 patients were to enable them as a recommendation. 10 Don't stop taking your medication. Go contact 11 your healthcare provider and decide with them what 12 course of action to take, which could be either 13 stay on those products, switch to another VCD 14 product that was not -- did not have the 15 impurities, or switch to another therapy 16 completely. 17 The reason they didn't recommend stop 18 taking that medication, because there were adverse 19 outcomes that could happen. Excuse me. I need a 20 drink here. 21 So the regulatory process that's been 22 set up in the industry was followed. The problem 23 was identified. The FDA was involved and 24 informed, and they took action through the 25 voluntary recalls to recall those products out of</p>	<p>Page 60</p> <p>1 the marketplace. So in the real world, you can't 2 just assume those things didn't happen. We have 3 to deal with the patients. We have to deal with 4 supply. We have to deal with alternatives. 5 In order to do that, you have to address 6 the problem. And you just can't say in an 7 alternative reality, oh, it's worthless and never 8 happened because that's not what, in fact, 9 happened. 10 BY MR. HONIK: 11 Q. Are you done? 12 A. Yes. 13 Q. The long answer that you just gave, is 14 that the substance of the conversation you had 15 with the four folks at AG regarding the 16 worthlessness analysis that Dr. Conti provided? 17 MR. DORNER: Object to form. 18 You can answer. 19 THE WITNESS: No. That's my conclusion 20 of Dr. Conti's analysis and my experience -- 21 BY MR. HONIK: 22 Q. I know it's your conclusion. The 23 question, sir -- 24 MR. DORNER: I'm sorry. I'm sorry. The 25 witness wasn't finished with his answer,</p> <p>Page 61</p> <p>1 Mr. Honik. 2 BY MR. HONIK: 3 Q. The question, Mr. Kosty -- 4 MR. DORNER: The witness was not 5 finished with his answer. Please let him finish. 6 BY MR. HONIK: 7 Q. Did you talk about the subjects -- 8 Mr. Kosty, here's the question. Did you talk 9 about the subjects that were in your elaborate 10 response with the four people at AG? Yes or no. 11 MR. DORNER: Objection. Form. 12 Mischaracterizes. And I'll note for the record 13 that opposing counsel didn't let the witness 14 finish his prior answer. 15 With that, you may answer. 16 THE WITNESS: No, because they don't 17 have the background in the industry that I do. 18 And, unfortunately, things happen, like I just 19 went through the explanation of the regulatory 20 safeguards in the industry with the FDA. They 21 don't have that background. I do. 22 I've worked with pharmacies. I've 23 worked with mail service pharmacies. I've worked 24 with PBMs. You have to address these issues as 25 they come up. And those issues were identified,</p>
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<p style="text-align: right;">Page 62</p> <p>1 fairly quickly were addressed and implemented in 2 the industry. So that's my opinion, that you just 3 can't say, oh, my gosh, if this never happened, 4 these products are worthless. 5 I see no documentation in this case that 6 would illustrate any patient did not receive the 7 therapeutic benefit of the VCD products they were 8 taking. So my conclusion is you just can't say, 9 well, this is how the world should work. This is 10 my alternative reality. You have to deal with how 11 the world actually works. 12 And how the world actually works is the 13 products were in commerce. They were identified 14 as issues. Those issues were addressed. 15 Processes were changed. And patients got on 16 alternative therapy or they got on VCD products 17 that didn't have the impurities. 18 That's the reality of the matter. And I 19 can't in my world where you have to deal with 20 these things wish it away. 21 BY MR. HONIK: 22 Q. Did you discuss this idea about the real 23 world that you've now twice explained to me with 24 the four folks at AG that you identified? 25 MR. DORNER: Objection. Vague.</p>	<p style="text-align: right;">Page 64</p> <p>1 MR. DORNER: Objection to the 2 characterization. 3 You may answer. 4 THE WITNESS: I spoke in a similar 5 manner about Ms. Craft's report. We -- 6 BY MR. HONIK: 7 Q. And -- I'm sorry. 8 A. Go ahead. That's fine. 9 Q. What did these folks convey to you at AG 10 about Laura Craft's opinions? 11 MR. DORNER: I'll caution not to divulge 12 the contents of any drafts that you may have 13 received. 14 THE WITNESS: I don't recall specific 15 conversations. Ms. Craft had another long report 16 that had many components to it. But I don't 17 recall the specific conversations. 18 BY MR. HONIK: 19 Q. Mr. Kosty, one of the things that needs 20 to be assured in this instance is that the report 21 which will be evaluated ultimately by the court 22 and potentially fact finders was authored by you. 23 So I'll ask you before moving on: Is 24 there any part of this report that reflects the 25 views of anyone at AG exclusively?</p>
<p style="text-align: right;">Page 63</p> <p>1 You can answer. 2 THE WITNESS: I don't recall if I 3 specifically addressed this issue or not. 4 BY MR. HONIK: 5 Q. And when you say you don't recall, does 6 that convey to me that you may have spoken with 7 the four folks at AG you identified about 8 Dr. Conti's economic worth analysis? 9 MR. DORNER: Objection to the 10 characterization. 11 You may answer. 12 THE WITNESS: I don't recall. I just 13 answered the same question. 14 BY MR. HONIK: 15 Q. And when you say you don't recall, does 16 that leave open the possibility that you may or 17 may not have? Is that fair? 18 MR. DORNER: Asked and answered. 19 You can answer. 20 THE WITNESS: Yes. It could be either 21 way. I don't recall. 22 BY MR. HONIK: 23 Q. Is it equally true that you spoke with 24 these four folks at AG about Laura Craft's 25 opinions in her report?</p>	<p style="text-align: right;">Page 65</p> <p>1 MR. DORNER: Object to form. Asked and 2 answered. Mischaracterizes. Argumentative. 3 You may answer. 4 THE WITNESS: The answer is no. 5 BY MR. HONIK: 6 Q. When you had this iterative exchange 7 with the folks at AG over drafts of this report, 8 would you get back written comments or track 9 changes or red lines to your draft? 10 MR. DORNER: Object to form. 11 Mischaracterizes. 12 You may answer. 13 THE WITNESS: It could have been via 14 conversation on a telephone call. There could 15 have been red line suggestions. Both of those 16 were alternatives that we discussed. 17 BY MR. HONIK: 18 Q. And the red lines and the suggestions 19 weren't limited to help in preparing tables. They 20 were red lines to language of your report; is that 21 correct? 22 A. I previously answered that question yes. 23 I told you we went through an edit process 24 iteration. I explained the methodology. It's the 25 same methodology now that it was half an hour ago.</p>

<p style="text-align: right;">Page 66</p> <p>1 Q. Was there anyone at your own consulting 2 firm that assisted you in writing this report? 3 A. No. 4 Q. And when in relation to its date, 5 namely, January 12, 2022, would you say it was 6 completed? 7 A. Probably January 11, 2022. 8 Q. And to whom did you send it initially 9 when it was complete? 10 A. It goes to counsel. 11 Q. And who did you send it to specifically? 12 Mr. Dorner? 13 A. Yes. 14 Q. Turn, if you would, in Exhibit 1, which 15 is your report, to page 9. 16 MR. DORNER: Actually, Ruben, we've been 17 going for about an hour. If this is on the same 18 topic, I'm fine with exploring and wrapping up 19 that topic, but then I think at that point it 20 might be a good time for our first break. 21 BY MR. HONIK: 22 Q. Mr. Kosty, do you need a break? 23 A. Yes. That would be great. 24 Q. Do you want five minutes now? 25 A. Sure.</p>	<p style="text-align: right;">Page 68</p> <p>1 that in the code. 2 BY MR. HONIK: 3 Q. And you're familiar with both of those 4 definitions in your extensive experience in the 5 pharma space; right? 6 A. Yes. 7 Q. Do you agree that U.S. pharmacies are 8 not permitted to sell drugs which are adulterated 9 under that FDA definition? 10 MR. DORNER: Objection. Outside the 11 scope. Calls for a legal conclusion. 12 You may answer. 13 THE WITNESS: Yeah. The pharmacies can 14 only purchase and the wholesalers only provide 15 approved FDA drugs. So they have to purchase 16 FDA-approved drugs. They don't have an option to 17 purchase nonFDA-approved drugs. 18 BY MR. HONIK: 19 Q. Right. And I appreciate that response 20 and I understand it. But I've asked a rather 21 specific question. 22 Do you agree that pharmacists in the 23 United States are prohibited from selling 24 adulterated drugs as defined by the FDA? 25 MR. DORNER: Objection. Asked and</p>
<p style="text-align: right;">Page 67</p> <p>1 Q. All right. Let's take five minutes. 2 We'll return at, let's call it, 15 after the hour. 3 THE VIDEOGRAPHER: Off record 11:09. 4 (Recess from 11:09 a.m. to 11:18 a.m.) 5 THE VIDEOGRAPHER: We are back on the 6 record at 11:18. 7 MR. DORNER: Ruben, I know it's faint 8 because the videographer is at the other end. We 9 went on 11:18. We're on. 10 MR. HONIK: Okay. I didn't hear anybody 11 or anything. 12 BY MR. HONIK: 13 Q. Mr. Kosty, do you agree that the FDA has 14 a specific definition of adulterated? 15 MR. DORNER: Objection. Outside the 16 scope. 17 You may answer. 18 THE WITNESS: Yes. There's a definition 19 of adulterated in the code, yes. 20 BY MR. HONIK: 21 Q. Do you agree that the FDA has a specific 22 definition of mislabeled? 23 MR. DORNER: Same objection. 24 You can answer. 25 THE WITNESS: Yes. They also define</p>	<p style="text-align: right;">Page 69</p> <p>1 answered. Calls for a legal conclusion. Outside 2 the scope. 3 You may answer. 4 THE WITNESS: When you say pharmacist 5 dispensed, the pharmacists are covered under the 6 state Board of Pharmacy regulations in all 50 7 states, and I have not looked at all 50 states to 8 see what those regulations are. So I don't know 9 off the top of my head if those regulations 10 address that or not. Like I said in my earlier 11 response, pharmacists can only order drugs that 12 have been approved by the FDA. 13 BY MR. HONIK: 14 Q. And I apologize if you didn't hear my 15 question. I didn't talk about dispensing. I 16 talked about selling. I'm asking you whether you 17 agree that no pharmacy -- no pharmacy or pharmacy 18 system can sell an adulterated drug in the class 19 of trade in the U.S. as defined by the FDA. Yes 20 or no. 21 MR. DORNER: Objection. Asked and 22 answered. This is the third time. The witness 23 cannot be required to give a "yes" or "no" answer. 24 He's permitted to explain. 25 MR. HONIK: Stop instructing him.</p>

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<p>1 MR. DORNER: It's not an instruction, 2 Ruben. It's the law of the case. 3 MR. HONIK: You're making a speaking 4 objection. 5 MR. DORNER: Do not talk over me, 6 Mr. Honik. Do not talk over me. It's very hard 7 for Ms. Medis to take all that down if you do. I 8 will restart. 9 Asked and answered a third time. The 10 witness cannot be required to give a "yes" or 11 "no." Calls for a legal conclusion. And outside 12 the scope. 13 You may answer. 14 THE WITNESS: Like I said, the pharmacy 15 can only purchase approved drugs. In this case, 16 they purchased the adulterated -- excuse me -- the 17 VCD drugs that had impurities. So they purchased 18 them. They were approved under ANDAs and they 19 were dispensed to patients. 20 So when you say the pharmacy sells, the 21 pharmacy dispenses drugs. That's how they sell 22 them to patients. 23 BY MR. HONIK: 24 Q. Mr. Kosty, you apparently read a lot of 25 deposition testimony in this case and you listed</p>	<p>1 Q. Did you read any testimony from any of 2 the retailers which confirmed that none of those 3 retail chains would sell adulterated drugs as 4 defined by the FDA? 5 MR. DORNER: Object to the 6 characterization. Objection. Outside the scope. 7 Vague. 8 You can answer. 9 THE WITNESS: I don't recall those 10 specifics. 11 BY MR. HONIK: 12 Q. And so if I suggested to you that each 13 and every one of them confirmed under oath that 14 none of those retail chains would or could sell 15 adulterated drugs as defined by the FDA, you'd 16 have no basis to deny that, would you? 17 MR. DORNER: Objection. 18 Mischaracterizes. Outside the scope. 19 You may answer. 20 THE WITNESS: No. I wouldn't have any 21 basis to object to their testimony if that's what 22 their testimony is. 23 BY MR. HONIK: 24 Q. And, similarly, you didn't read any 25 testimony from any of the retailer defendants that</p>
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<p>1 it in your reliance material; right? 2 A. Yes. 3 Q. Did you read any of the testimony from 4 30(b)(6) witnesses proffered by the retailers in 5 this case? 6 MR. DORNER: Object to form. 7 You can answer. 8 THE WITNESS: I'm not sure from a legal 9 perspective what's a 30(b)(6) witness. I read 10 declarations from the pharmacy executives about 11 their business practices. 12 BY MR. HONIK: 13 Q. Um-hum. Did you read any testimony from 14 any of the retailer defendants in this case? 15 A. Yes. 16 MR. DORNER: Objection. Vague. 17 You can answer. 18 THE WITNESS: Yes. 19 BY MR. HONIK: 20 Q. Which ones did you read? 21 A. I think I cite a number of them in my 22 report. The one that I recall offhand is the lady 23 from Kroger's. Her last name is Britt, I believe, 24 or first name. But, yeah, I did read some of 25 those testimonies.</p>	<p>1 confirmed that they would never sell mislabeled 2 drugs as defined by the FDA, would you? 3 MR. DORNER: Objection. Compound. 4 Outside the scope. 5 You can answer. 6 THE WITNESS: I don't recall those 7 specifics. 8 BY MR. HONIK: 9 Q. You agree that the FDA has the power 10 through its regulatory enforcement to identify 11 drugs which are adulterated as defined by them as 12 well as mislabeled; correct? 13 MR. DORNER: Objection. Compound. 14 Calls for a legal conclusion. Outside the scope. 15 Mischaracterizes. 16 You may answer. 17 THE WITNESS: Yes. 18 BY MR. HONIK: 19 Q. Turn, if you would, to page 9 of your 20 report, section D that's called Assignment. 21 A. Yes. 22 Q. And I take it in paragraph 24, this 23 describes what you were asked to do by the 24 defendants in this case; right? 25 A. Yes.</p>

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<p>1 Q. The first sentence up till that first 2 semicolon I take to be background material or 3 information, right, explain the factors and 4 practices in the industry; is that correct? 5 MR. DORNER: Objection. Compound. 6 You can answer. 7 THE WITNESS: Yeah. It's more than 8 background on the pharmaceutical industry. 9 Someone on the call is not on mute. 10 BY MR. HONIK: 11 Q. Sorry for the interruption. Continue 12 your answer. 13 A. So it's more than background 14 information. It's information on how the industry 15 works in practice. 16 Q. Okay. And then what follows after that 17 semicolon are the, I'll say, four specific 18 assignments that you undertook; right? 19 MR. DORNER: Objection to the 20 characterization. 21 You can answer. 22 THE WITNESS: Yes. 23 BY MR. HONIK: 24 Q. The first is to describe presumably the 25 complexities that are relevant to the assessment</p>	<p>1 BY MR. HONIK: 2 Q. Class membership, if you're in or out of 3 the class, you looked at data on that question; 4 did you not? 5 A. I did, yes. 6 Q. That was one of your claimed 7 assignments; correct? 8 A. Yes. 9 Q. The third thing that you did to look at 10 available data to allow someone to calculate the 11 amount of impurities to which a patient might have 12 been exposed. Did you do that? 13 A. Yes. 14 Q. How did you do that? 15 A. I looked at the specifics in this case 16 with the impurities in the different lots. Then I 17 looked at the industry to see could we identify by 18 patient what potential impurities they may have 19 ingested in taking the VCD products at issue. So 20 I looked at that. 21 I looked at the DSCSA, which is a 22 10-year long implementation of the law which 23 really had two components to it. One component 24 was to prevent and make very difficult for the 25 introduction of counterfeit drug products into the</p>
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<p>1 of injury; right? 2 A. Yes. 3 Q. The second is the extent to which data 4 is available to allow someone to identify class 5 membership; right? 6 MR. DORNER: Objection to the 7 characterization. You're not reading the entirety 8 of the paragraph. 9 MR. HONIK: Nor am I trying to. Stop 10 interrupting. 11 MR. DORNER: I'm allowed to make an 12 objection, Mr. Honik. Don't interrupt me. 13 BY MR. HONIK: 14 Q. Mr. Kosty, was that the second thing 15 that you tried to do -- 16 MR. DORNER: Objection. 17 BY MR. HONIK: 18 Q. -- to discuss available data to identify 19 class membership? 20 MR. DORNER: Objection. 21 Mischaracterizes. 22 You can answer. 23 THE WITNESS: It was to -- let me see 24 the specific verbiage -- was to include class 25 members and also class exclusions.</p>	<p>1 supply chain. And the second component of that 2 law was to provide the ability for the industry in 3 the event of a recall to be able to track a 4 recalled product down to the patient level. 5 So this law from 2013 to 2023, it's a 6 rolling implementation over that timeframe. That 7 law has not been fully implemented, not until 8 November of 2023. The ability to track a specific 9 lot to a patient is not available in the industry 10 today. So when I looked at could we track to an 11 individual patient the specific lot numbers and 12 the impurities potentially ingested, could that be 13 done, my conclusion is no, it can't be done given 14 the state of the industry today. 15 Q. So I gather from your answer that FDA 16 regulations and federal law impacted your 17 analysis; correct? 18 MR. DORNER: Objection to the 19 characterization. 20 You can answer. 21 THE WITNESS: Yeah, it mischaracterizes 22 it. The DSCSA is the law that I looked at and 23 understand. I don't know if there's other federal 24 regulations that pertain to this. But the DSCSA 25 implementation obviously has been a big issue in</p>

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<p>1 the industry since 2013 when it was passed.</p> <p>2 So there's been a whole process involved</p> <p>3 with supply chain participants having discussions</p> <p>4 in the industry to determine, A, how can we comply</p> <p>5 with this, B, what are the operational</p> <p>6 alternatives for compliance and, C how do we work</p> <p>7 with our trading partners to implement so we can</p> <p>8 comply with these regulations.</p> <p>9 So this has been an ongoing process for</p> <p>10 nine or ten years now to decide as an industry how</p> <p>11 do you implement these complex regulations. So</p> <p>12 it's an ongoing process. It's iterative.</p> <p>13 Business partners can agree to do things one way.</p> <p>14 They can agree to do things another way. The</p> <p>15 industry consortiums that are looking at these</p> <p>16 implementation issues are trying to understand</p> <p>17 what's the best way to do that so it's effective</p> <p>18 and most cost effective for all the participants.</p> <p>19 So, like I said, it's an ongoing process.</p> <p>20 BY MR. HONIK:</p> <p>21 Q. Mr. Kosty, I just wanted to know if the</p> <p>22 law impacted your analysis.</p> <p>23 MR. DORNER: Objection. Vague.</p> <p>24 You may answer.</p> <p>25 THE WITNESS: Yes. The DSCSA impacted</p>	<p>1 certain on the record that none of your opinions</p> <p>2 go to the liability part of this case, correct,</p> <p>3 that is, whether the defendants did anything wrong</p> <p>4 or right as to the VCDs; right?</p> <p>5 MR. DORNER: Objection. Compound.</p> <p>6 Mischaracterizes.</p> <p>7 You can answer.</p> <p>8 THE WITNESS: Yes, that's correct.</p> <p>9 BY MR. HONIK:</p> <p>10 Q. What you did is really confined to</p> <p>11 commenting in the areas we've now described with</p> <p>12 respect to damages, on the one hand, and</p> <p>13 ascertaining class membership, on the other; is</p> <p>14 that correct?</p> <p>15 MR. DORNER: Same objections.</p> <p>16 You can answer.</p> <p>17 THE WITNESS: Those were the primary</p> <p>18 focuses of my report, yes.</p> <p>19 BY MR. HONIK:</p> <p>20 Q. Fair enough. Now, this last assignment</p> <p>21 that I just read to you that you agreed I read</p> <p>22 correctly, do you agree that you'd have to</p> <p>23 understand on what legal basis defendants may be</p> <p>24 found liable to answer the question and determine</p> <p>25 if reliable data exists to estimate damages?</p>
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<p>1 my analysis.</p> <p>2 BY MR. HONIK:</p> <p>3 Q. And did other FDA regulations impact</p> <p>4 your analysis?</p> <p>5 A. No.</p> <p>6 Q. Did you say "no"?</p> <p>7 A. I said no.</p> <p>8 Q. The fourth item that you discussed among</p> <p>9 your assignments is the "extent to which data are</p> <p>10 available and sufficient to reliably estimate</p> <p>11 damages on a class-wide basis in the event any</p> <p>12 defendants are found liable."</p> <p>13 Do you see that sentence?</p> <p>14 A. Yes.</p> <p>15 Q. Did I read that correctly?</p> <p>16 A. You did.</p> <p>17 Q. First, is it true that you offer no</p> <p>18 opinions on defendants' liability?</p> <p>19 A. That is true. I critiqued the</p> <p>20 plaintiffs' experts' reports.</p> <p>21 Q. You concede that -- I'm sorry. I spoke</p> <p>22 over you. What?</p> <p>23 A. I critiqued the plaintiffs' experts'</p> <p>24 that I was assigned to look at reports.</p> <p>25 Q. Right. And I'm just trying to be</p>	<p>1 MR. DORNER: Objection. Vague. Calls</p> <p>2 for a legal conclusion. Mischaracterizes.</p> <p>3 You may answer.</p> <p>4 THE WITNESS: No. I am not an attorney.</p> <p>5 I'm not in the legal profession. I looked at this</p> <p>6 from an industry perspective.</p> <p>7 BY MR. HONIK:</p> <p>8 Q. Right. And I get that. You've</p> <p>9 expressed that to me, and I accepted that's what</p> <p>10 you did.</p> <p>11 A. Right.</p> <p>12 Q. But I'm asking a slightly different</p> <p>13 question. In order to comment on whether there is</p> <p>14 data that's sufficient to reliably estimate</p> <p>15 damages, don't you need to understand the legal</p> <p>16 basis upon which one or more of these defendants</p> <p>17 may be found liable?</p> <p>18 MR. DORNER: Same objections.</p> <p>19 BY MR. HONIK:</p> <p>20 Q. Yes or no.</p> <p>21 MR. DORNER: Same objection.</p> <p>22 You can answer.</p> <p>23 THE WITNESS: No, because I'm looking at</p> <p>24 the data as an industry perspective, not a legal</p> <p>25 perspective.</p>

<p>Page 82</p> <p>1 BY MR. HONIK:</p> <p>2 Q. Well, let me ask you this: Do you think</p> <p>3 whether a defendant is liable under principles,</p> <p>4 for example, of warranty versus unjust enrichment</p> <p>5 impact your assignment?</p> <p>6 MR. DORNER: Objection. Calls for a</p> <p>7 legal conclusion. Outside the scope. And vague.</p> <p>8 You may answer.</p> <p>9 THE WITNESS: No. It does not impact my</p> <p>10 evaluation of available data in this case.</p> <p>11 BY MR. HONIK:</p> <p>12 Q. Did you consider in any way, shape or</p> <p>13 form in any of your analyses whether a defendant</p> <p>14 might be liable under one or an alternative theory</p> <p>15 of legal liability?</p> <p>16 MR. DORNER: Objection. Outside the</p> <p>17 scope. Calls for a legal conclusion.</p> <p>18 You may answer.</p> <p>19 THE WITNESS: No.</p> <p>20 BY MR. HONIK:</p> <p>21 Q. And so specifically when you drill down</p> <p>22 to answer the question is there reliable data to</p> <p>23 estimate damages, you didn't consider at all</p> <p>24 whether that liability attaches in a theory of</p> <p>25 warranty breach or unjust enrichment; correct?</p>	<p>Page 84</p> <p>1 You can answer.</p> <p>2 THE WITNESS: Yes. I'm not here to make</p> <p>3 a legal conclusion based on the legal terms that</p> <p>4 you just stated. I'm here to provide an opinion</p> <p>5 in my industry expertise on the available data and</p> <p>6 what potentially could that show or not show.</p> <p>7 That was the basis for my critiques of Dr. Conti's</p> <p>8 economic report.</p> <p>9 BY MR. HONIK:</p> <p>10 Q. Did you understand in reading</p> <p>11 Dr. Conti's report that she was asked to make</p> <p>12 certain assumptions?</p> <p>13 MR. DORNER: Objection to</p> <p>14 mischaracterization.</p> <p>15 You may answer if you know.</p> <p>16 THE WITNESS: Yes. She was instructed</p> <p>17 to make a lot of assumptions that really limited</p> <p>18 her focus to that alternative reality that she</p> <p>19 worked in.</p> <p>20 BY MR. HONIK:</p> <p>21 Q. And tell me in as clear a way as you can</p> <p>22 what alternative reality you're referring to when</p> <p>23 you use that phrase.</p> <p>24 A. Well, she assumes that the products are</p> <p>25 worthless. She assumes that there is no supply</p>
<p>Page 83</p> <p>1 MR. DORNER: Objection. Compound.</p> <p>2 Calls for a legal conclusion. Vague. And</p> <p>3 mischaracterizes.</p> <p>4 You may answer.</p> <p>5 THE WITNESS: I did not look at the</p> <p>6 legal definitions of all those different legal</p> <p>7 terms to inform my analysis of the data. I looked</p> <p>8 at it again from an industry perspective.</p> <p>9 BY MR. HONIK:</p> <p>10 Q. When you received this assignment, were</p> <p>11 you asked to make any assumptions by anyone?</p> <p>12 A. Not in this area, no. I don't recall</p> <p>13 any assumptions I was asked to make. My</p> <p>14 assignment is pretty straightforward, the</p> <p>15 different areas. But, no, I was not asked to make</p> <p>16 assumptions in it.</p> <p>17 Q. You've said to me repeatedly, Mr. Kosty,</p> <p>18 that you looked at this from an industry</p> <p>19 perspective. Do you remember telling me that?</p> <p>20 A. Yes.</p> <p>21 Q. And can you tell me why you think that's</p> <p>22 a proper way to answer the assignments or</p> <p>23 questions that you delineate on page 9, paragraph</p> <p>24 24 of your report?</p> <p>25 MR. DORNER: Objection. Vague.</p>	<p>Page 85</p> <p>1 curve for those products. She assumes that the</p> <p>2 retailers and wholesalers dispense those products</p> <p>3 knowing that they had impurities. So she's</p> <p>4 created the sandbox where anything outside of</p> <p>5 that, it's not of importance to her.</p> <p>6 Q. You reject those assumptions; is that</p> <p>7 correct?</p> <p>8 A. Yes. In my analysis, I do reject those</p> <p>9 assumptions because, as I explained earlier, in</p> <p>10 the real world it works differently, and we have</p> <p>11 to deal with those things.</p> <p>12 Q. In addition to reviewing Dr. Conti's</p> <p>13 report, did you read her testimony from her</p> <p>14 deposition?</p> <p>15 A. I read a draft, rough draft of it, and I</p> <p>16 skimmed through her testimony, yes.</p> <p>17 Q. Were you directed to read specific parts</p> <p>18 of it by anyone?</p> <p>19 A. No.</p> <p>20 Q. Turn, if you would, to Appendix C of</p> <p>21 Exhibit 1, your report, which is the listing of</p> <p>22 materials you relied upon.</p> <p>23 A. What page in Exhibit C?</p> <p>24 Q. The page is delineated C-1, your</p> <p>25 Appendix C.</p>

<p style="text-align: right;">Page 86</p> <p>1 A. Yes.</p> <p>2 Q. Earlier in your report you actually</p> <p>3 state that you relied upon certain court filings;</p> <p>4 isn't that right?</p> <p>5 A. Yes, and they're listed here.</p> <p>6 Q. And there are seven listed documents</p> <p>7 that you claim to have relied upon in helping to</p> <p>8 form your opinions; correct?</p> <p>9 A. Yes.</p> <p>10 Q. Are these the only seven court filings</p> <p>11 or court documents that you relied upon apart from</p> <p>12 depositions and the like?</p> <p>13 MR. DORNER: Objection. Vague.</p> <p>14 You can answer.</p> <p>15 THE WITNESS: Yes.</p> <p>16 BY MR. HONIK:</p> <p>17 Q. Did you select these seven court</p> <p>18 filings?</p> <p>19 A. No. Defense counsel selected those for</p> <p>20 my review based on their legal expertise. I would</p> <p>21 have no basis of understanding the legal process</p> <p>22 and all the motions and back and forth attorneys</p> <p>23 do from a pharmacist and industry perspective.</p> <p>24 So, no, I relied on counsel to provide</p> <p>25 me the documentations they felt relevant in my</p>	<p style="text-align: right;">Page 88</p> <p>1 Q. Take a look at footnote 43.</p> <p>2 A. Okay. Yes. I'm at the footnote.</p> <p>3 Q. Is that the footnote that refers to the</p> <p>4 reliance material letter that we looked at in</p> <p>5 Appendix C?</p> <p>6 A. In addition to the declaration of Megan</p> <p>7 Mistarz from Walgreens.</p> <p>8 Q. And your reliance on it, is it limited</p> <p>9 to this idea that open pharmacy networks have</p> <p>10 higher reimbursement rates?</p> <p>11 A. In referencing the section, yes, but I</p> <p>12 also read it for general knowledge on the</p> <p>13 background of the case.</p> <p>14 Q. Meaning you read the letter that was</p> <p>15 sent in on this issue to the court on macro</p> <p>16 discovery; correct?</p> <p>17 A. Yes.</p> <p>18 MR. DORNER: Object to form.</p> <p>19 You can answer.</p> <p>20 BY MR. HONIK:</p> <p>21 Q. What else did you extract from the</p> <p>22 letter that you relied upon?</p> <p>23 A. I don't recall the specifics from that</p> <p>24 letter. If I recall correctly, it was about a</p> <p>25 hundred pages.</p>
<p style="text-align: right;">Page 87</p> <p>1 assignment.</p> <p>2 Q. And in what way did you rely upon the</p> <p>3 retailer pharmacy defendants' letter Re: Macro</p> <p>4 Discovery Disputes, which is the fifth item that</p> <p>5 you list as a reliance material?</p> <p>6 A. I would have to find out the exact</p> <p>7 footnote that references this to answer that</p> <p>8 question. If you want to give me a couple of</p> <p>9 minutes to find it, I will.</p> <p>10 But the gist of that letter was, I</p> <p>11 guess, there were discovery disputes and</p> <p>12 objections on what was to be disclosed, and my</p> <p>13 recollection --</p> <p>14 MR. DORNER: I'm sorry. The witness</p> <p>15 wasn't finished quite. I'm sorry.</p> <p>16 THE WITNESS: My recollection was this</p> <p>17 document explained that back and forth between, I</p> <p>18 guess, the retailers and the plaintiffs'</p> <p>19 attorneys.</p> <p>20 BY MR. HONIK:</p> <p>21 Q. Can you find the footnote that you think</p> <p>22 references that reliance material?</p> <p>23 A. Give me a minute to find that material.</p> <p>24 I'm trying to narrow it down to the area of the</p> <p>25 report where I discuss the pharmacy data.</p>	<p style="text-align: right;">Page 89</p> <p>1 Q. You think it was a hundred-page letter?</p> <p>2 A. If it's the one that I believe was</p> <p>3 referenced here, yes, it was about a hundred-page</p> <p>4 letter.</p> <p>5 Q. Mr. Kosty, there are nearly 2000 docket</p> <p>6 entries in this case. Do you have any idea or can</p> <p>7 you tell me why this one letter was sent to you?</p> <p>8 MR. DORNER: Objection. Asked and</p> <p>9 answered. Calls for speculation. And</p> <p>10 mischaracterizes.</p> <p>11 You may answer.</p> <p>12 THE WITNESS: I recall asking for this</p> <p>13 background on what the retailers' issues were with</p> <p>14 the data.</p> <p>15 BY MR. HONIK:</p> <p>16 Q. What do you mean retailer issues?</p> <p>17 A. My understanding, if I recall the</p> <p>18 letter -- and as you rightly point out, there's</p> <p>19 hundreds of documents in this case, so to recall</p> <p>20 specifically -- but my recollection is it was a</p> <p>21 back and forth on what information would be</p> <p>22 disclosed.</p> <p>23 Q. Sir, the seven court filings and only</p> <p>24 seven that you rely upon, six of them are briefs</p> <p>25 or memos that counsel provided. This is the only</p>

<p style="text-align: right;">Page 90</p> <p>1 letter.</p> <p>2 Can you tell me why this is the only</p> <p>3 letter upon which you rely?</p> <p>4 MR. DORNER: Same objection.</p> <p>5 THE WITNESS: No.</p> <p>6 MR. HONIK: Why don't we mark and bring</p> <p>7 up the June 16, 2020 letter that Mr. Kosty claims</p> <p>8 to have relied on and mark that Exhibit 2.</p> <p>9 (Kosty Exhibit 2 was marked.)</p> <p>10 THE WITNESS: Do I need to download</p> <p>11 these or something, or how does this work?</p> <p>12 MR. DORNER: I believe if we refresh</p> <p>13 your screen, it should appear.</p> <p>14 THE WITNESS: How does one refresh the</p> <p>15 screen?</p> <p>16 MR. DORNER: That mouse is live. You</p> <p>17 can use the mouse to navigate as you need.</p> <p>18 BY MR. HONIK:</p> <p>19 Q. Do we have that on the share screen?</p> <p>20 MR. DORNER: I don't see it, Ruben.</p> <p>21 MR. HONIK: Dave, Layne, can somebody</p> <p>22 bring it up?</p> <p>23 MR. STANOCH: The letter is available</p> <p>24 and marked as Exhibit 2. This is David Stanoch.</p> <p>25 I could share my screen if that would help.</p>	<p style="text-align: right;">Page 92</p> <p>1 to the use of an incomplete exhibit.</p> <p>2 MR. HONIK: Thank you.</p> <p>3 BY MR. HONIK:</p> <p>4 Q. Let us know when you're ready to answer,</p> <p>5 Mr. Kosty.</p> <p>6 Mr. Kosty, are you ready to respond to</p> <p>7 my question?</p> <p>8 A. I'm still looking through the document,</p> <p>9 counselor.</p> <p>10 Q. Let me know when you're done.</p> <p>11 A. Will do. Okay.</p> <p>12 Q. Do you remember the question?</p> <p>13 A. How did I rely on this in my report?</p> <p>14 Q. Correct.</p> <p>15 A. The reliance is in terms of the</p> <p>16 confidentiality nature of the PBM agreements that</p> <p>17 both parties -- the retailers and the PBMs hold</p> <p>18 these documents close to the vest as very</p> <p>19 confidential. It outlines the business</p> <p>20 arrangement between those parties.</p> <p>21 Q. Is that your complete response?</p> <p>22 A. Yes.</p> <p>23 Q. In what way does the confidentiality</p> <p>24 which is claimed to attach to those PBM agreements</p> <p>25 impact any of your opinions?</p>
<p style="text-align: right;">Page 91</p> <p>1 MR. HONIK: Thank you.</p> <p>2 BY MR. HONIK:</p> <p>3 Q. Mr. Kosty, this is page 1 of what's now</p> <p>4 marked Exhibit 2 that you listed as a reliance</p> <p>5 document from among the court filings. It's dated</p> <p>6 June 16, 2020. It's a letter authored by Sarah</p> <p>7 Johnston at Barnes & Thornburg on behalf of one or</p> <p>8 more retailers.</p> <p>9 Does this refresh your recollection</p> <p>10 about this letter upon which you relied?</p> <p>11 A. This does refresh my recollection. And</p> <p>12 my earlier recollection was incorrect. This is a</p> <p>13 different document.</p> <p>14 MR. DORNER: And I do want to note for</p> <p>15 the record this letter comes with many</p> <p>16 attachments, as I understand it. So these</p> <p>17 attachments are not part of Exhibit 2 that's been</p> <p>18 entered by plaintiffs' counsel.</p> <p>19 BY MR. HONIK:</p> <p>20 Q. Mr. Kosty, do you remember now seeing</p> <p>21 this and in what way you relied upon this letter?</p> <p>22 A. Give me a moment to go through here.</p> <p>23 Q. Sure. Take your time.</p> <p>24 MS. KAPKE: This is Kara Kapke for CVS</p> <p>25 and Rite Aid. I just want to lodge an objection</p>	<p style="text-align: right;">Page 93</p> <p>1 A. In this section of the report, this was</p> <p>2 the background on the industry, and it's</p> <p>3 explaining why these things are confidential and</p> <p>4 kept close to the vest. So it informed my opinion</p> <p>5 in terms of how it's used in the industry and that</p> <p>6 all parties to the agreement believe they're</p> <p>7 highly confidential.</p> <p>8 Q. What is it about the confidential or</p> <p>9 claimed confidential nature of PBM agreements</p> <p>10 impacts any of your opinions in this case?</p> <p>11 A. It impacts on what the actual rates were</p> <p>12 paid to those pharmacies both at the point of</p> <p>13 adjudication, and then subsequent to the</p> <p>14 adjudication, whether there's adjustments to it</p> <p>15 made through a DIR fee. There might be a</p> <p>16 withhold. There might be a performance network</p> <p>17 payment for certain metrics that are achieved.</p> <p>18 So all those different types of terms</p> <p>19 and conditions are documented in these agreements</p> <p>20 between the parties. And it's not surprising to</p> <p>21 me that they've put up a fight to not disclose</p> <p>22 those documents.</p> <p>23 Q. So accepting as true that those</p> <p>24 arrangements or PBM contracts may or may not</p> <p>25 reflect differing rates, my question is: What is</p>

<p style="text-align: right;">Page 94</p> <p>1 it about their confidentiality which you claim you 2 relied upon impacts any of your opinions? 3 A. The section here I use as a citation is 4 the background on the industry to explain why 5 they're important, but it doesn't impact my 6 opinions further on in the report, just basic 7 industry knowledge that these documents are highly 8 confidential. 9 Q. Sir, turn to the page 4 of this exhibit 10 marked 2 now, page 4 of the letter, under Roman 11 III. Argument, heading A, which reads, 12 "Disgorgement of profits is not an available 13 remedy to plaintiffs." Do you see that? 14 A. Yes. 15 Q. Didn't you rely upon that statement in 16 authoring your report? 17 MR. DORNER: Objection to both the form 18 and also to the use of an incomplete exhibit. 19 You may answer if you can. 20 THE WITNESS: I did not use this 21 document in that analysis, no. 22 BY MR. HONIK: 23 Q. Well, I didn't ask you that. I asked 24 you whether you assumed that disgorgement of 25 profits is not an available remedy to plaintiffs</p>	<p style="text-align: right;">Page 96</p> <p>1 in this deposition, I'm not an attorney. I'm not 2 in the legal profession. When I critiqued 3 Dr. Conti's methodology, I'm doing it from a 4 business perspective, as I say in my report. 5 So I did not include any legal arguments 6 in my analysis. It was of no importance to me in 7 my report. I'm looking at her methodology from a 8 business perspective, and that's where my comments 9 are taken from. 10 BY MR. HONIK: 11 Q. Do you know what disgorgement of profits 12 means? 13 A. Not from a legal perspective, no. 14 Q. From any perspective. From that of a 15 pharmacist with an MBA. 16 A. Disgorgement would be to give them back, 17 the profit back. Certainly in this section A, it 18 doesn't say what the profit is or how it's 19 calculated, and that goes the gist of my argument 20 against the methodology proposed. 21 Q. What do you mean by that? 22 A. I mean Dr. Conti does not take into 23 account the cost associated. In the retailer 24 example in this section, this Exhibit 2, she just 25 assumes whatever happened at the point of sale is</p>
<p style="text-align: right;">Page 95</p> <p>1 in authoring your report. Yes or no. 2 MR. DORNER: Same objection. 3 You can answer. 4 THE WITNESS: I did not, no. 5 BY MR. HONIK: 6 Q. You understood that the retailers in 7 this document and others made that argument; 8 correct? 9 MR. DORNER: Objection. Outside the 10 scope. 11 You may answer if you can. 12 THE WITNESS: No. I don't understand 13 that because I didn't read it for that legal 14 perspective. 15 BY MR. HONIK: 16 Q. Sir, I'm confused. How can you comment 17 on a methodology for calculating damages if you 18 don't understand or attempt to understand whether 19 disgorgement of profits is a proper measure of 20 damages? 21 MR. DORNER: Objection. Calls for a 22 legal conclusion. Vague. 23 You may answer. 24 THE WITNESS: It calls for a legal 25 conclusion. I don't -- like I've said many times</p>	<p style="text-align: right;">Page 97</p> <p>1 the cost to the retailer. It's so ludicrous that 2 she doesn't even include the cost of the drug in 3 her analysis. 4 So if there's no cost of the drug, then 5 what in the world could a patient pick up if there 6 was no product there? So obviously the pharmacy 7 had to account and purchase those products they 8 can dispense to patients. They have to hire staff 9 to run their pharmacies. They have to hire a 10 pharmacist. They have to hire technicians. They 11 hire clerical people. They hire front end people. 12 They have rent. They have leases they 13 have to pay for. I'm sorry I'm going too fast. 14 They have all these other operating costs, heat, 15 light, upkeep, to provide services to patients 16 when they come into the pharmacies. 17 Dr. Conti includes none of those in her 18 methodology. So I went and looked in the industry 19 because the cost of dispensing is an important 20 concept, especially in the Medicaid arena where 21 the Medicaid programs have gone to NADAC plus 22 dispensing fee. So NADAC is more an estimate of 23 the product cost. So states were required to 24 conduct a cost of dispensing survey. 25 And so NACDS, as I reference in my</p>

<p style="text-align: right;">Page 98</p> <p>1 report, published a survey that indicated it was 2 \$12.40 per prescription cost to fill those 3 prescriptions. Dr. Conti accounts for none of 4 those costs. Again, another assumption is that 5 that product is magically there for a patient and 6 doesn't consider all these other operating costs 7 that retailers have to have in order to provide 8 services to patients. 9 So that's the basis of my business 10 review of her methodology for retailers. 11 Q. Mr. Kosty, do you think you need to 12 understand what the point of injury is to comment 13 on the damages available in this case? 14 MR. DORNER: Object to form. Calls for 15 a legal conclusion. Vague. 16 You may answer. 17 THE WITNESS: The way I look at this is 18 there's a -- the way the case -- my understanding 19 is there's an allegation that those patients were 20 harmed. I see no documentation that indicates 21 that they were harmed from a pharmacist/healthcare 22 perspective. The point of sale is one moment in 23 time. All these adjustments that have been after 24 the fact need to be accounted for. 25 I don't know your answer from a legal</p>	<p style="text-align: right;">Page 100</p> <p>1 You may answer if you can. 2 THE WITNESS: Yes. My opinions did not 3 depend on any legal understanding of those terms. 4 BY MR. HONIK: 5 Q. Did you ever have an understanding that 6 there needs to be a connection between theory of 7 liability and calculation of damages in cases such 8 as this that you've been asked to work on? Did 9 anybody tell you that? 10 MR. DORNER: Objection. Compound. 11 Calls for a legal conclusion. 12 You may answer. 13 THE WITNESS: It was outside the scope 14 of my assignment. 15 BY MR. HONIK: 16 Q. And you don't have any idea or view 17 about whether the legal theories supporting a 18 claim of damages is connected; correct? 19 MR. DORNER: Objection. Vague. Calls 20 for a legal conclusion. 21 You may answer. 22 THE WITNESS: I don't have an 23 understanding of the legal ramifications of those 24 terms. 25</p>
<p style="text-align: right;">Page 99</p> <p>1 perspective. From a business perspective, the 2 initial engagement with the healthcare system is 3 when that patient, at least in this example, gets 4 their prescription filled in the retail pharmacy. 5 BY MR. HONIK: 6 Q. Mr. Kosty, do you think it matters in 7 calculating class-wide economic damages to 8 understand when the harm occurred in the eyes of 9 the law? 10 MR. DORNER: Same objection. 11 You may answer. 12 THE WITNESS: Again, I did not look at 13 this issue from a legal perspective. I looked at 14 it from a practical business perspective. And as 15 I just went through, the components that are 16 required for a pharmacy to be operational and 17 dispensing prescriptions are many and numerous and 18 costly. 19 BY MR. HONIK: 20 Q. And you've already confirmed that in no 21 way did the theory of liability, whether pursued 22 under warranty or unjust enrichment or any theory 23 legally, weighed in on your opinions; correct? 24 MR. DORNER: Objection. Asked and 25 answered. Mischaracterizes.</p>	<p style="text-align: right;">Page 101</p> <p>1 BY MR. HONIK: 2 Q. Take a look at page 7 of this exhibit. 3 Do you see the paragraph that begins with the 4 language, "Put another way, to the extent the 5 consumer plaintiffs have suffered no actual harm 6 (because, for instance, they had no copay for 7 valsartan) they have no standing to bring any type 8 of economic loss claim." 9 Do you see that sentence? 10 A. Yes. 11 Q. Did you adopt that assumption in writing 12 your report? 13 MR. DORNER: Objection. Asked and 14 answered. 15 You may answer. 16 THE WITNESS: No. 17 BY MR. HONIK: 18 Q. Do you agree that the plaintiffs have no 19 economic loss and have suffered no actual harm? 20 MR. DORNER: Objection to the extent it 21 calls for a legal conclusion. Compound. Outside 22 the scope. 23 You may answer. 24 THE WITNESS: So in the case the 25 sentence that says patients that had no copay,</p>

<p style="text-align: right;">Page 102</p> <p>1 they had zero out-of-pocket expense for the 2 valsartan prescription. So from an economic 3 perspective, they had no payment to the pharmacy 4 for that prescription. So there's no copay. So 5 it's zero. 6 But from a legal perspective, like I 7 just mentioned, I don't have an opinion one way or 8 another on it. 9 BY MR. HONIK: 10 Q. Sir, do you have a belief that consumer 11 plaintiffs who purchased contaminated or 12 adulterated VCDs have no economic harm? Is that 13 your view? 14 MR. DORNER: Objection. 15 Characterization. Vague. Form. 16 You may answer if you can. 17 THE WITNESS: That was not part of my 18 assignment to evaluate that. 19 BY MR. HONIK: 20 Q. You did look at Dr. Conti's report which 21 expressed the view that there was economic harm 22 that those class members suffered; correct? 23 A. Yes. 24 Q. And at a high level, you don't agree 25 with that opinion; right?</p>	<p style="text-align: right;">Page 104</p> <p>1 BY MR. HONIK: 2 Q. Yeah. Let me rephrase it. 3 Do you think it matters what the court's 4 legal view is about how to measure damages in this 5 case? 6 MR. DORNER: Objection. Calls for a 7 legal conclusion. Form. Vague. 8 You may answer. 9 THE WITNESS: It does matter what the 10 court says, but it didn't matter to me in my 11 assignment, in my report, what those legal 12 decisions may or may not be. My assignment was 13 from an industry perspective to comment on these 14 four topics we previously went through. 15 BY MR. HONIK: 16 Q. I totally get that your perspective was 17 limited or confined to what you describe as the 18 industry perspective. But before I dig deeper 19 into this point, I'm just trying to understand 20 whether it would matter to your analysis, albeit 21 limited to the industry, to know and understand 22 how the court views the proper calculation of 23 damages might occur. 24 MR. DORNER: Objection. 25</p>
<p style="text-align: right;">Page 103</p> <p>1 MR. DORNER: Objection. Vague. 2 You may answer. 3 THE WITNESS: Yes. 4 BY MR. HONIK: 5 Q. And so the question naturally devolves 6 to: Do you believe that there was any economic 7 harm to consumers of contaminated or adulterated 8 VCDs during the class period? 9 MR. DORNER: Objection. 10 Characterization. Vague. Calls for a legal 11 conclusion. Outside the scope. Compound. 12 You may answer. 13 THE WITNESS: That's outside the scope 14 of my assignment. 15 BY MR. HONIK: 16 Q. Sir, is it, in your view, outside of the 17 purview of what should inform your opinion to 18 understand what the court's view of the right 19 measure of damages may be in this case? 20 MR. DORNER: Objection. Vague. And to 21 form. 22 You can answer if you understand. 23 THE WITNESS: Could you repeat that 24 again, counselor? 25</p>	<p style="text-align: right;">Page 105</p> <p>1 BY MR. HONIK: 2 Q. Yes or no. 3 MR. DORNER: Objection. 4 Mischaracterizes. Outside the scope. Calls for a 5 legal conclusion. Form. Vague. And compound. 6 You may answer. 7 THE WITNESS: It was outside the scope 8 of my assignment. And, no, I didn't look at the 9 legal issues that you just described. 10 BY MR. HONIK: 11 Q. And it was of no moment to you in 12 writing your report to understand what the proper 13 criteria would be under the law to calculate 14 economic damages for consumer plaintiffs or TPPs; 15 correct? 16 MR. DORNER: Objection. Lacks 17 foundation. Calls for a legal conclusion. Vague. 18 And calls for a legal conclusion. 19 You may answer. 20 THE WITNESS: Yes. It was of no moment 21 for me to evaluate those issues. As I said 22 previously, I looked at them from an industry 23 perspective. 24 MR. HONIK: Let's mark as Exhibit 3 25 Judge Kugler's Motion to Dismiss Opinion 3</p>

<p>Page 106</p> <p>1 Regarding Warranty Claims. If you can bring that 2 up, that would be great. 3 MR. DORNER: Ruben, would you mind if I 4 either showed Mr. Kosty how to refresh the exhibit 5 folder or do it for him? Would that bother you? 6 MR. HONIK: You can do whatever you 7 like. 8 (Kosty Exhibit 3 was marked.) 9 BY MR. HONIK: 10 Q. We'll mark this Exhibit 3, Mr. Kosty. I 11 did not see this listed in your Appendix C of 12 Exhibit 1, your report, that this was a material 13 you relied upon. Is that right? 14 A. Yes. 15 Q. So the defense lawyers that engaged you 16 to write your report never produced it so that you 17 could read it; right? 18 A. Yes. 19 Q. And are you looking at this for the 20 first time ever? 21 A. Yes. 22 Q. I want to represent to you that what a 23 motion to dismiss opinion is is a ruling by the 24 court on the sufficiency in this case of the 25 complaint or the amended complaint which you did</p>	<p>Page 108</p> <p>1 court's view on the question of how to measure 2 economic worth as it relates to the claims 3 asserted in this case, did you? 4 A. I did not. 5 Q. If you turn with me in Exhibit 3 to page 6 20 of the court's opinion, I want to point some 7 language out to you. 8 Do you see the second paragraph that 9 begins with the words, "This court finds"? 10 A. I'll still getting there. Page 20? 11 Q. Yes, sir. Are you there? 12 A. I'm there now. Okay. 13 Q. Do you see the paragraph that begins 14 with the words "This court finds"? 15 A. Yes. 16 Q. It reads, and I quote, "This court finds 17 that contaminated drugs are economically worthless 18 at the point of sale by virtue of the 19 dangerousness caused by their contamination 20 regardless whether the sold VCDs actually achieved 21 the medical purpose of lowering blood pressure." 22 Did I read that correctly? 23 A. You did. 24 Q. And do you understand now that that 25 principle articulated by the court, albeit in this</p>
<p>Page 107</p> <p>1 look at; correct? 2 A. Yes. 3 Q. And, in fact, you quite accurately 4 listed the allegations that plaintiff make in the 5 complaint against the various defendants here; 6 right? 7 A. Yes. 8 Q. So I represent to you that this is an 9 expression of the court's view about whether those 10 allegations sufficiently lay out an actionable and 11 cognizable legal claim. Do you understand that? 12 MR. DORNER: I'll object to the 13 characterization. And this is really legal 14 testimony. 15 But you can answer. 16 THE WITNESS: Can you explain what a 17 cognizable legal claim is? 18 BY MR. HONIK: 19 Q. Sure. Plaintiffs make allegations in a 20 complaint, and what the court does is accept them 21 as true for the purposes of determining whether 22 they lay out a proper legal claim. 23 Do you understand that? 24 A. Yes. 25 Q. Okay. And so you didn't look at the</p>	<p>Page 109</p> <p>1 context, was something we asked Dr. Conti to 2 assume? Do you understand that? 3 MR. DORNER: Objection to the 4 characterization of the court opinion. Object to 5 form. Compound. Calls for a legal conclusion. I 6 think that's it. 7 You can answer if you understand. 8 THE WITNESS: I'm unaware of any 9 conversations between plaintiffs' attorneys and 10 Dr. Conti on this issue. 11 BY MR. HONIK: 12 Q. Right. But you read her report and you 13 understood that the underpinning of her economic 14 analysis is predicated on the fact that she was 15 asked to assume that the drugs were adulterated as 16 defined by the FDA and that there was no sale 17 curve that would give the drugs any value. You 18 understand that, don't you? 19 MR. DORNER: Objection. Compound. 20 You can answer. 21 THE WITNESS: Yes. She states that as 22 one of her assumptions in her report, yes. 23 BY MR. HONIK: 24 Q. And you can see for yourself that the 25 court tracks that assumption in this opinion; do</p>

<p style="text-align: right;">Page 110</p> <p>1 you not?</p> <p>2 MR. DORNER: Objection.</p> <p>3 Mischaracterizes the opinion. Calls for a legal</p> <p>4 conclusion.</p> <p>5 You may answer.</p> <p>6 THE WITNESS: Yes.</p> <p>7 BY MR. HONIK:</p> <p>8 Q. You see the second sentence that</p> <p>9 follows, it says, "Put differently, contaminated</p> <p>10 drugs, even if medically efficacious for their</p> <p>11 purpose, cannot create a benefit of the bargain</p> <p>12 because the contaminants and their dangerous</p> <p>13 effects were never bargained for."</p> <p>14 Do you see that?</p> <p>15 A. Yes.</p> <p>16 Q. And do you understand that principle to</p> <p>17 be that when you are sold or purchase an</p> <p>18 adulterated drug, that you're not getting the</p> <p>19 benefit of the bargain? Do you understand that?</p> <p>20 MR. DORNER: Objection.</p> <p>21 Mischaracterizes. Outside the scope. Calls for a</p> <p>22 legal conclusion. Compound and vague.</p> <p>23 You may answer.</p> <p>24 THE WITNESS: I don't know what -- can</p> <p>25 you explain to me from a legal perspective what</p>	<p style="text-align: right;">Page 112</p> <p>1 I have done."</p> <p>2 BY MR. HONIK:</p> <p>3 Q. Mr. Kosty, you confirm that you made no</p> <p>4 economic conclusions in your report; correct?</p> <p>5 MR. DORNER: Objection.</p> <p>6 Characterizations.</p> <p>7 You can answer if you can.</p> <p>8 THE WITNESS: I think it</p> <p>9 mischaracterizes my economic conclusions based on</p> <p>10 my industry analysis of those additional</p> <p>11 associated costs with both the pharmacies, the</p> <p>12 retailers and the wholesalers.</p> <p>13 BY MR. HONIK:</p> <p>14 Q. Sir, the last sentence reads, "Further,</p> <p>15 contaminated drugs do create a present injury</p> <p>16 because their sale should never have occurred."</p> <p>17 Do you see that?</p> <p>18 A. Yes.</p> <p>19 Q. Did you take that statement into account</p> <p>20 in any of your analyses in your report?</p> <p>21 A. I did not.</p> <p>22 Q. You understand that if legally the sale</p> <p>23 of these adulterated drugs should not have</p> <p>24 occurred, that that impacts their economic worth?</p> <p>25 MR. DORNER: Objection. Calls for a</p>
<p style="text-align: right;">Page 111</p> <p>1 the benefit of the bargain is?</p> <p>2 BY MR. HONIK:</p> <p>3 Q. Is it correct that the persons who</p> <p>4 engaged you to write your report never explained</p> <p>5 that principle to you?</p> <p>6 A. Yes.</p> <p>7 Q. And so, therefore, you couldn't possibly</p> <p>8 have any economic insight into whether benefit of</p> <p>9 the bargain damages exist in this case or not, can</p> <p>10 you?</p> <p>11 MR. DORNER: Objection.</p> <p>12 Mischaracterizes. Argumentative. Compound. And</p> <p>13 vague. And calls for a legal conclusion.</p> <p>14 You may answer.</p> <p>15 THE WITNESS: My assignment was not to</p> <p>16 make economic conclusions, but to evaluate the</p> <p>17 economic -- Conti's calculations from a business</p> <p>18 perspective, and that's what I have done.</p> <p>19 MR. HONIK: Can I have the answer read</p> <p>20 back.</p> <p>21 (The following record was read back:</p> <p>22 "THE WITNESS: My assignment was</p> <p>23 not to make economic conclusions, but to</p> <p>24 evaluate the economic -- Conti's calculations</p> <p>25 from a business perspective, and that's what</p>	<p style="text-align: right;">Page 113</p> <p>1 legal conclusion. Mischaracterizes. Outside the</p> <p>2 scope.</p> <p>3 You can answer.</p> <p>4 THE WITNESS: I don't have a legal</p> <p>5 opinion on this. But from a business perspective,</p> <p>6 those products were sold and were dispensed to</p> <p>7 patients.</p> <p>8 BY MR. HONIK:</p> <p>9 Q. Do you deny that they should not have</p> <p>10 been?</p> <p>11 MR. DORNER: Objection. Calls for</p> <p>12 speculation. Lack of foundation. Again,</p> <p>13 mischaracterizes. Calls for a legal conclusion.</p> <p>14 Vague. I think that's all of them.</p> <p>15 THE WITNESS: I think in this case, if</p> <p>16 it was known before these products were on the</p> <p>17 market -- the FDA has the duty to identify</p> <p>18 products and regulate them as safe and effective.</p> <p>19 If this information was known before those</p> <p>20 products were launched into the marketplace, then</p> <p>21 my expectation is the FDA would not have approved</p> <p>22 those products.</p> <p>23 In fact, they were approved and were</p> <p>24 launched into the marketplace and the pharmacies</p> <p>25 dispensed them, unbeknownst to them, that they had</p>

<p style="text-align: right;">Page 114</p> <p>1 impurities and the wholesalers distributed them, 2 unbeknownst to them, there were impurities. And 3 that's how they got into the market. 4 Assuming perfect information and all 5 that was known up front before this happened, my 6 expectation would be those products would not have 7 been available because the FDA would not have 8 approved them. 9 BY MR. HONIK: 10 Q. You will agree that the FDA prohibits 11 the introduction or delivery into interstate 12 commerce any prescription drug that is adulterated 13 or misbranded? 14 MR. DORNER: Objection. Calls for a 15 legal conclusion. Outside the scope. 16 You can answer. 17 THE WITNESS: I don't know the specific 18 FDA regulation, but my understanding would be 19 those drugs, if they were misbranded and 20 adulterated, would not be approved. 21 BY MR. HONIK: 22 Q. Well, we're not talking about approval. 23 We're talking about whether you accept as true 24 that the FDA specifically prohibits the 25 introduction of adulterated or misbranded drugs</p>	<p style="text-align: right;">Page 116</p> <p>1 legal conclusion. Mischaracterization. Outside 2 the scope. Vague. And I think compound. 3 You may answer. 4 THE WITNESS: No, I did not. 5 BY MR. HONIK: 6 Q. Are you, in fact, familiar with the 7 listing of FDA's prohibited acts as it concerns 8 prescription drugs? 9 MR. DORNER: Objection to vague. 10 You can answer. 11 THE WITNESS: Not at a detailed level 12 because that's not my area of expertise in terms 13 of regulatory compliance. But as a pharmacist, 14 yes, you have an understanding of those 15 requirements. 16 BY MR. HONIK: 17 Q. Sir, do you understand that Dr. Conti 18 looked at this with care and is the very 19 foundation of her damage analysis, mainly that 20 these drugs were improperly introduced into the 21 stream of commerce because they were adulterated 22 and misbranded as defined by the FDA? 23 MR. DORNER: Objection. Compound. 24 Lacks foundation. Mischaracterizes. Vague. 25 You can answer.</p>
<p style="text-align: right;">Page 115</p> <p>1 into interstate commerce. Yes or no. 2 MR. DORNER: Same objections. And the 3 witness is entitled to an explanation. 4 THE WITNESS: Yes. The FDA would 5 prohibit those if they had known about them. But 6 in this case, they did not know about them. 7 BY MR. HONIK: 8 Q. Did you consider that prohibition in any 9 of your analysis in your report? 10 MR. DORNER: Objection to the extent it 11 calls for a legal conclusion. Outside the scope. 12 You may answer. 13 THE WITNESS: No, I did not because, as 14 I stated previously, these things did happen and 15 the industry, as I explained earlier, had the 16 regulatory mechanism to identify and respond to 17 them and conduct the voluntary recalls. So, no, I 18 did not take that into account in my answer or my 19 report. 20 BY MR. HONIK: 21 Q. And is it true that you also didn't take 22 into account that those prohibited drugs that are 23 either adulterated or misbranded cannot be 24 proffered for pay or otherwise? 25 MR. DORNER: Objection. Calls for a</p>	<p style="text-align: right;">Page 117</p> <p>1 THE WITNESS: I have no foundation as to 2 what Dr. Conti considered besides the report that 3 she provided. 4 BY MR. HONIK: 5 Q. Well, did you consider foundational to 6 your expressed opinions what the FDA's views are 7 on the placement of prohibited adulterated, 8 misbranded drugs in the stream of commerce? Did 9 that in any way weigh on your opinions? 10 MR. DORNER: Objection. Lacks 11 foundation. 12 You can answer. 13 THE WITNESS: No, it did not. I looked 14 at the formularies for calculating unjust 15 enrichment for both retailers and the wholesalers, 16 and my comments were limited to those formulas. 17 MR. HONIK: Let's mark as Exhibit 4 and 18 bring up 21 U.S.C.A. Section 331. 19 (Kosty Exhibit 4 was marked.) 20 THE WITNESS: Is that Exhibit 4? 21 MR. HONIK: It's going to be marked 22 Exhibit 4. 23 BY MR. HONIK: 24 Q. Have you seen this before today? 25 A. No.</p>

<p style="text-align: right;">Page 118</p> <p>1 Q. Part of the Food and Drug Act.</p> <p>2 A. No. I have not reviewed this prior to</p> <p>3 this.</p> <p>4 Q. No. I've asked a different question.</p> <p>5 In your 38 years of experience, have you ever seen</p> <p>6 this act?</p> <p>7 A. Oh, yes, of course.</p> <p>8 Q. And have you seen this specific section</p> <p>9 that defines with particularity prohibited acts by</p> <p>10 the FDA?</p> <p>11 MR. DORNER: Objection to</p> <p>12 characterization.</p> <p>13 You can answer.</p> <p>14 THE WITNESS: I've reviewed the FDA act,</p> <p>15 certain parts of it based upon our consulting</p> <p>16 projects and the need to know certain information.</p> <p>17 But for this case, I did not specifically go and</p> <p>18 read the FDA's Food, Drug and Cosmetics Act.</p> <p>19 BY MR. HONIK:</p> <p>20 Q. Let me unpack that. For this report</p> <p>21 that you prepared in valsartan that we're here to</p> <p>22 talk about today, you didn't look at any of the</p> <p>23 FDA regulations. Is that what you're saying?</p> <p>24 A. No. That mischaracterizes my statement.</p> <p>25 I did go and look at the specific definitions of</p>	<p style="text-align: right;">Page 120</p> <p>1 FDA prohibits the placement of an adulterated or</p> <p>2 misbranded drug into the stream of commerce;</p> <p>3 correct?</p> <p>4 MR. DORNER: Objection. Calls for a</p> <p>5 legal conclusion. Characterization.</p> <p>6 You can answer.</p> <p>7 THE WITNESS: I don't know the answer to</p> <p>8 that because the way I read this, the</p> <p>9 introduction, in my mind, it's the introduction, a</p> <p>10 known introduction of a product that meets these</p> <p>11 criteria. If I don't know there's an issue, then</p> <p>12 I could have, like in this case, introduced that</p> <p>13 product not knowing that it was -- had an impurity</p> <p>14 into it.</p> <p>15 So the way I interpret this, it doesn't</p> <p>16 say it, but knowingly introducing. If I don't</p> <p>17 know there's an issue, then I wouldn't know I was</p> <p>18 potentially violating this.</p> <p>19 BY MR. HONIK:</p> <p>20 Q. Sir, you don't list this among your</p> <p>21 reliance materials; right?</p> <p>22 A. That's correct.</p> <p>23 Q. And you don't disagree that whether one</p> <p>24 knows it or doesn't know it, this prohibited act</p> <p>25 is not in any way qualified by that. It simply</p>
<p style="text-align: right;">Page 119</p> <p>1 misbranded and adulterated.</p> <p>2 Q. Okay. Apart from that, did you look at</p> <p>3 anything else pertaining to FDA's regulations and</p> <p>4 rules?</p> <p>5 A. Not in terms of reviewing this FD&C Act,</p> <p>6 but I did -- not in terms of regulations. I did</p> <p>7 review, like I mentioned earlier, the website that</p> <p>8 gave us the chronology of the nitrosamines issue.</p> <p>9 Q. Right. But I'm talking about FDA</p> <p>10 regulations. Did you look at any besides the two</p> <p>11 you mentioned, namely, the definition of</p> <p>12 adulterated and misbranded?</p> <p>13 A. I did not.</p> <p>14 Q. This one reads, "The following acts and</p> <p>15 the costing thereof are prohibited." Do you see</p> <p>16 that?</p> <p>17 A. Yes.</p> <p>18 Q. And the very first thing listed at (a)</p> <p>19 is "The introduction or delivery for introduction</p> <p>20 into interstate commerce of any food, drug,</p> <p>21 device, tobacco product or cosmetic that is</p> <p>22 adulterated or misbranded."</p> <p>23 Did I read that correctly?</p> <p>24 A. Yes.</p> <p>25 Q. And that means in plain English that the</p>	<p style="text-align: right;">Page 121</p> <p>1 states that you can't put an adulterated or</p> <p>2 misbranded product, drug product into the stream</p> <p>3 of commerce. That is what it says; correct?</p> <p>4 MR. DORNER: Objection. Compound.</p> <p>5 Calls for a legal conclusion. Outside the scope.</p> <p>6 And mischaracterizes.</p> <p>7 You may answer.</p> <p>8 THE WITNESS: Yes. That's what it says.</p> <p>9 BY MR. HONIK:</p> <p>10 Q. And that's synonymous or the same as</p> <p>11 saying that there's no legitimate supply curve.</p> <p>12 That is, you can't legally introduce into the</p> <p>13 legal class of trade an adulterated or misbranded</p> <p>14 drug product; correct?</p> <p>15 MR. DORNER: Objection.</p> <p>16 Mischaracterizes. Lacks foundation. Calls for a</p> <p>17 legal conclusion. Let me see the question.</p> <p>18 BY MR. HONIK:</p> <p>19 Q. Your answer, sir?</p> <p>20 MR. DORNER: I'm sorry. I was making</p> <p>21 sure that my objection was complete. I apologize,</p> <p>22 Mr. Honik.</p> <p>23 BY MR. HONIK:</p> <p>24 Q. Your answer, Mr. Kosty?</p> <p>25 MR. DORNER: I'm sorry. I'm confirming</p>

<p style="text-align: right;">Page 122</p> <p>1 my objection is complete. 2 BY MR. HONIK: 3 Q. Your answer, Mr. Kosty? 4 MR. DORNER: You may answer. 5 THE WITNESS: Yes. 6 BY MR. HONIK: 7 Q. And if you look with me at (c), the 8 prohibited acts are even more specific. It says, 9 and I quote, "The receipt in interstate commerce 10 of any food, drug, device, tobacco product or 11 cosmetic that is adulterated on misbranded and the 12 delivery or proffered delivery for pay or 13 otherwise." 14 Do you see that? 15 A. Yes. 16 Q. And so the FDA act here is specific in 17 saying that you cannot exchange for money an 18 adulterated or misbranded product that you placed 19 into the stream of commerce; correct, sir? 20 MR. DORNER: Objection. Calls for a 21 legal conclusion. Outside the scope. And 22 mischaracterizes. 23 You can answer. 24 THE WITNESS: Yes. That's how it's 25 written.</p>	<p style="text-align: right;">Page 124</p> <p>1 and, therefore, subject to this prohibition of 2 placing them in interstate commerce? 3 MR. DORNER: Objection. 4 Mischaracterizes. Calls for a legal conclusion. 5 You may answer. 6 THE WITNESS: Yes. That was one of the 7 assumptions in the Conti report. 8 BY MR. HONIK: 9 Q. Correct. Do you know what the word 10 syllogism means? 11 A. No. 12 Q. It's where you take one element and add 13 another element and perhaps more and you arrive at 14 a conclusion or assumption. 15 Accepting that definition of syllogism, 16 do you understand that what Dr. Conti did was to 17 accept as true that these valsartan-containing 18 drugs were as defined by the FDA adulterated and 19 mislabeled and, therefore, subject to this 20 prohibition where you couldn't place them into the 21 stream of commerce? 22 Do you understand that? 23 MR. DORNER: Same objections. 24 You can answer. 25 THE WITNESS: I understand that's one of</p>
<p style="text-align: right;">Page 123</p> <p>1 BY MR. HONIK: 2 Q. And you told me that you're familiar 3 with the FDA definition of adulterated and 4 misbranded; right? 5 A. Yes. 6 Q. And do you understand and accept that an 7 adulterated and misbranded product can be one that 8 was not subject to appropriate cGMPs? 9 MR. DORNER: Objection. Outside the 10 scope. Calls for a legal conclusion. 11 Mischaracterizes. 12 You may answer. 13 THE WITNESS: Yeah, that's the outside 14 the scope my expertise. I'm not a cGMP expert. 15 BY MR. HONIK: 16 Q. Do you, nonetheless, understand in your 17 experience in the pharmacy area that failure of 18 cGMP can be a basis upon which the FDA finds a 19 drug to be adulterated or misbranded? 20 MR. DORNER: Same objections. 21 THE WITNESS: Yes. 22 BY MR. HONIK: 23 Q. And are you aware in reading Dr. Conti's 24 report that she was asked to assume that the drugs 25 were, in fact, adulterated and misbranded here</p>	<p style="text-align: right;">Page 125</p> <p>1 the assumptions she made in her report, yes. 2 BY MR. HONIK: 3 Q. Okay. Now, Mr. Kosty, if you were asked 4 by the court to serve as an expert witness in this 5 case, you wouldn't turn down that opportunity if 6 presented, would you? 7 MR. DORNER: Objection. Form. Vague. 8 Lacks foundation. Calls for speculation. 9 You can answer. 10 THE WITNESS: Maybe. It depends. It 11 depends on what other projects I would have going 12 on at the time whether or not I would accept 13 another legal assignment, because it's been my 14 experience working on these cases that they're 15 very time consuming and you have deadlines that 16 just are all encompassing in terms of work 17 activity. 18 So I'd evaluate if I had the bandwidth 19 to take on another project or not. 20 BY MR. HONIK: 21 Q. That's fair and I understand your 22 response. Here's the beauty of these 23 examinations. 24 I want you to assume, Mr. Kosty, that 25 the court has given you that assignment and you've</p>

<p style="text-align: right;">Page 126</p> <p>1 accepted it and the court is asking you to assess 2 damages in this case and only that. And I want 3 you to further assume that the court has 4 instructed you in the face of a demonstration that 5 the VCDs in question were adulterated and 6 mislabeled and, therefore, should never have been 7 in the marketplace, that there was a failure of 8 the bargain to be satisfied and your job is to 9 calculate the damages at the point of sale. 10 Do you understand that hypothetical? 11 A. Yes. 12 MR. DORNER: I'll object to -- 13 BY MR. HONIK: 14 Q. How would you go -- 15 MR. DORNER: I'm sorry. I will object 16 to an incomplete hypothetical, to compound, to 17 mischaracterizing and to calling for a legal 18 conclusion. 19 You may ask the next question. 20 BY MR. HONIK: 21 Q. How would you then calculate the damages 22 for consumers at the point of sale? 23 MR. DORNER: Objection. Outside the 24 scope. Incomplete hypothetical. 25 Mischaracterizes.</p>	<p style="text-align: right;">Page 128</p> <p>1 at the point of sale, what would you do as to 2 those damages? What would you look at? 3 MR. DORNER: Same objections plus 4 incomplete hypothetical. 5 You may answer. 6 THE WITNESS: I would need further 7 research to do that. I would have to identify 8 legal -- in this case what a TPP is and identify 9 who that TPP was responsible for that 10 prescription. 11 BY MR. HONIK: 12 Q. You know that at the point of sale when 13 there's a prescription, a VCD dispensed, it's 14 known instantly in that financial transaction how 15 much an insurer paid and how much the consumer 16 paid; correct? 17 A. No, that is not correct. All you know 18 at the point of sale at the pharmacy is how much 19 to collect from the patient and what PBM is 20 responsible for paying the pharmacist. 21 Q. And the amount -- 22 MR. DORNER: I'm sorry. I'm sorry. 23 Mr. Kosty wasn't finished with his answer. We've 24 also been going for an hour and ten here. So I'd 25 ask for a break at some point.</p>
<p style="text-align: right;">Page 127</p> <p>1 You may answer. 2 THE WITNESS: The only information at 3 the point of sale concerning a patient on when a 4 prescription is adjudicated is the amount of 5 copay. 6 MR. DORNER: And I'll likewise add an 7 objection to calling for a legal conclusion. I 8 apologize. Please keep going. 9 BY MR. HONIK: 10 Q. So you agree that if one could determine 11 the amount of a copay or co-insurance at the point 12 of sale for a consumer buying a contaminated or 13 adulterated VCD, that would be the proper measure 14 of their damages under my hypothetical; correct? 15 MR. DORNER: Objection. Calls for a 16 legal conclusion. Outside the scope. 17 Mischaracterizes. 18 You may answer. 19 THE WITNESS: Yes. That would be the 20 only information you would have, at the point of 21 sale. 22 BY MR. HONIK: 23 Q. That's right. And if you were asked 24 under a similar hypothetical to calculate what the 25 TPPs or insurers paid as part of that transaction</p>	<p style="text-align: right;">Page 129</p> <p>1 But, Mr. Kosty, please finish you 2 answer. 3 THE WITNESS: So what the pharmacy 4 knows -- and you got to think about what does the 5 pharmacy care about. The pharmacy was presented a 6 prescription drug card from the patient. The 7 pharmacy enters certain information into their 8 computer system. They adjudicate the claim. They 9 know what PBM is responsible for paying them. 10 So as long as the PBM makes payment to 11 that pharmacy, they don't need to know any 12 information further than that. In my experience, 13 running a third party for Rite-Aid and Thrift 14 Drug, it did not matter who the TPP was. It only 15 mattered if that PBM that we had the contractual 16 relationship paid their claims. And if they did 17 that, we were satisfied, and that was all we 18 needed to know. And it's very straightforward 19 from a pharmacy perspective. The PBM pays us, and 20 we relieve our receivable. 21 BY MR. HONIK: 22 Q. It is straightforward such that at the 23 point of adjudication, one knows in an insured 24 situation how much the consumer has to pay and how 25 much the insurer is paying; correct?</p>

<p style="text-align: right;">Page 130</p> <p>1 MR. DORNER: Same objections.</p> <p>2 THE WITNESS: The pharmacy doesn't know</p> <p>3 who the payor is outside the PBM. And your</p> <p>4 characterization that's the insurance company is</p> <p>5 inaccurate. The PBM may be contracted with a</p> <p>6 self-insured employer. They could have a</p> <p>7 contractual relationship with another PBM. They</p> <p>8 could have a relationship with a TPA.</p> <p>9 So there's all different opportunities</p> <p>10 for relationships. All the pharmacy knows is that</p> <p>11 PBM is responsible for the payment to them.</p> <p>12 BY MR. HONIK:</p> <p>13 Q. Sir, and I apologize because I don't</p> <p>14 think I made my question clear enough. It's not</p> <p>15 consequential what the pharmacy knows. I'm asking</p> <p>16 about data that's created at the point of</p> <p>17 adjudication.</p> <p>18 You agree, do you not, that every single</p> <p>19 time an American picks up a prescription who</p> <p>20 happens to be insured, there is data collected</p> <p>21 that exists somewhere that reveals how much the</p> <p>22 consumer paid, that is, the patient, and how much</p> <p>23 his or her insurance company contributed? That</p> <p>24 data exists; correct?</p> <p>25 MR. DORNER: Objection. Argumentative</p>	<p style="text-align: right;">Page 132</p> <p>1 pharmacy.</p> <p>2 BY MR. HONIK:</p> <p>3 Q. Sir, if a cash customer, an uninsured</p> <p>4 customer pays cash for any prescription drug, that</p> <p>5 amount is known; correct?</p> <p>6 A. Yes.</p> <p>7 MR. DORNER: And, Ruben, I do want to</p> <p>8 jump in. I could use a break here soon as well.</p> <p>9 MR. HONIK: We're almost done. Stop</p> <p>10 interrupting me for now.</p> <p>11 MR. DORNER: Ruben, please. I'm asking</p> <p>12 for a break. It's a civil matter.</p> <p>13 MR. HONIK: We're not going to take a</p> <p>14 break right now. I have several more questions.</p> <p>15 MR. DORNER: I'm not asking you to stop</p> <p>16 now.</p> <p>17 MR. HONIK: Excuse me?</p> <p>18 MR. DORNER: I'm not asking you to stop</p> <p>19 now. I'm asking shortly I could use a break.</p> <p>20 MR. HONIK: Stop interrupting me. I</p> <p>21 heard you the first time. We'll stop when I want</p> <p>22 to stop. We're near the end.</p> <p>23 BY MR. HONIK:</p> <p>24 Q. Mr. Kosty, inasmuch as you know what the</p> <p>25 cash payor pays, isn't it true the data exists</p>
<p style="text-align: right;">Page 131</p> <p>1 and lacks foundation. Vague. Compound. And</p> <p>2 mischaracterizes.</p> <p>3 You may answer.</p> <p>4 THE WITNESS: So the point of sale, as</p> <p>5 I've stated before, is the transaction between the</p> <p>6 pharmacy and the patient and the PBM. So the PBM</p> <p>7 now has that transaction. Let's just assume for</p> <p>8 argument's sake that that transaction has been</p> <p>9 completed and the PBM is in possession of it.</p> <p>10 So now the PBM has to bill their client.</p> <p>11 And the way the PBMs are set up, they have a</p> <p>12 number of different business models, the first one</p> <p>13 being a transparent pass-through, and that means</p> <p>14 that the PBM is going to bill their customer,</p> <p>15 whoever that may be which could include an</p> <p>16 insurance company, the amount paid at the</p> <p>17 pharmacy. So it's transparent. It's a</p> <p>18 pass-through price.</p> <p>19 The other model that PBMs employ is</p> <p>20 called a traditional spread model. And what the</p> <p>21 PBMs do is take whatever that transaction amount</p> <p>22 is at the pharmacy and they add a markup to it</p> <p>23 before they bill their customer. So the amount</p> <p>24 the PBM ultimately pays may be different than what</p> <p>25 is adjudicated at the point of sale at the</p>	<p style="text-align: right;">Page 133</p> <p>1 that is knowable as to the amount an insured</p> <p>2 consumer pays, what his or her share is, and what</p> <p>3 the insurance company paid and what their share</p> <p>4 is? That is data that is available today; is it</p> <p>5 not?</p> <p>6 MR. DORNER: Objection. Vague.</p> <p>7 Compound. Argumentative. Lacks foundation. And</p> <p>8 mischaracterizes.</p> <p>9 You may answer.</p> <p>10 THE WITNESS: Yeah, the data would be</p> <p>11 available if you knew what party to go ask for it.</p> <p>12 BY MR. HONIK:</p> <p>13 Q. Do you agree that IQVIA collects the</p> <p>14 very datapoints that we're discussing now, mainly</p> <p>15 the amount of payments by consumers and TPPs for</p> <p>16 prescription drugs in America?</p> <p>17 MR. DORNER: Object to characterization.</p> <p>18 You may answer.</p> <p>19 THE WITNESS: Yes. IQVIA buys data from</p> <p>20 various entities in the pharmaceutical industry.</p> <p>21 And the purpose of the IQVIA data is to provide</p> <p>22 trend information to market participants. It's</p> <p>23 also used in the pharmaceutical industry to track</p> <p>24 from a brand pharmaceutical manufacturer</p> <p>25 perspective their salesforce effectiveness.</p>

<p style="text-align: right;">Page 134</p> <p>1 So if I'm a salesman in a certain 2 territory, say Pittsburgh, and I'm promoting a 3 product, then the IQVIA data is used to track the 4 performance of that drug product in my sales 5 territory. So there's a lot of uses of the IQVIA 6 data that's typically aggregated. You can't go 7 and look at individual claims from them. That's 8 not part of their business model. 9 BY MR. HONIK: 10 Q. You agree that IQVIA data is the gold 11 standard that's used day in and day out in the 12 pharmaceutical industry; correct? 13 A. Yes. It's the leading provider of that 14 data, although there are other alternatives you 15 could purchase. 16 MR. HONIK: We can take a break now. 17 How much time do you want, Drew? 18 MR. DORNER: It's up to Mr. Kosty. Five 19 or ten? 20 THE WITNESS: My question, when are we 21 going to plan to break for lunch? 22 MR. DORNER: Is now a good time, Ruben? 23 MR. HONIK: We can do that if you'd 24 like. It's 12:36. What time do you want to 25 resume?</p>	<p style="text-align: right;">Page 136</p> <p>1 A. Yes. I'm there. 2 Q. And if I'm reading your report 3 correctly, the subparts to paragraph 31 beginning 4 with (a) and going through several pages 5 concluding in (e) are the various specific ways in 6 which you disagree with Dr. Conti and her views; 7 right? 8 A. Yes. 9 Q. And in 31(a), we sort of talked about 10 this, this is the part of her conclusions that I 11 think you described as being in an unreal or 12 fantasy world. Do you remember that? 13 A. I do. 14 Q. And the reason you made those statements 15 previously is because you place a value on the 16 clinical or therapeutic benefit of even these 17 contaminated drugs; right? 18 A. I haven't used the word contaminated. 19 The ones with impurity, yes, I do place a clinical 20 value on them. 21 Q. Well, I hate to retrench and go back 22 over territory I thought we had reached agreement 23 to, but the definition of adulterated is specific 24 and defined by the FDA; correct? 25 MR. DORNER: Object to form. Legal</p>
<p style="text-align: right;">Page 135</p> <p>1 MR. DORNER: Do you want a half hour or 2 do you want a little longer? 3 THE WITNESS: 1:15. 4 MR. HONIK: 1:15 we'll resume. Thank 5 you. 6 THE VIDEOGRAPHER: Off the record 12:36. 7 (Recess from 12:36 p.m. to 1:19 p.m.) 8 THE VIDEOGRAPHER: We're back on the 9 record at 1:19. 10 BY MR. HONIK: 11 Q. Mr. Kosty, good afternoon. I presume 12 you had a satisfactory lunch break and you're 13 ready to proceed now? 14 A. Yes. 15 Q. Before we took our lunch break, we were 16 talking about in lawyerly terms the benefit of the 17 bargain theory and the proper criteria for 18 assessing damages in this case. 19 Do you remember that? 20 A. Yes. 21 Q. And that's a topic that you took 22 Dr. Conti to task in your report; did you not? 23 A. I did. 24 Q. Can you turn with me to Exhibit 1, which 25 is your report, paragraph 31 appearing on page 13.</p>	<p style="text-align: right;">Page 137</p> <p>1 conclusion. 2 THE WITNESS: Yes. 3 BY MR. HONIK: 4 Q. And you accept that that is the 5 operative definition that we have to work under 6 when we speak about adulterated drugs; correct? 7 A. Yes. 8 Q. In other words, we can't make up our own 9 definition of adulterated; correct? 10 A. Correct. 11 Q. And I'm happy to spend some time doing 12 so, but you agree that adulteration can occur 13 where the FDA decides there's noncompliance with 14 current good manufacturing practices; correct? 15 MR. DORNER: Objection to form. Asked 16 and answered. Calls for a legal conclusion. 17 THE WITNESS: I don't know all the 18 remedies the FDA has in their armamentarium. What 19 they could do, I don't know for sure from a 20 regulatory perspective. 21 BY MR. HONIK: 22 Q. Let's take a moment and talk about this 23 before we continue because I see that there may be 24 some gap in our shared knowledge and experience 25 about this.</p>

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1 MR. HONIK: Dave, can you bring up the
2 FDA warning letter, the first of them for, say,
3 ZHP.
4 MR. DORNER: Are you entering this as an
5 exhibit?
6 MR. HONIK: Yep. Are we up to five?
7 MR. DORNER: That's what I have.
8 (Kosty Exhibit 5 was marked.)
9 BY MR. HONIK:
10 Q. Mr. Kosty, I apologize, but I don't
11 think this was among the reliance materials that
12 you cited; correct?
13 A. Correct.
14 Q. And for the benefit of the record,
[REDACTED]

Page 139

[REDACTED]

Page 140

[REDACTED]

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[REDACTED]

8 BY MR. HONIK:
9 Q. Okay. So if we're now talking about as
10 defined adulterated drugs according to the FDA, by
11 reason of a failure to maintain current good
12 manufacturing practices, you certainly understand
13 that that can form a basis for a drug being
14 defined as adulterated; correct?
15 MR. DORNER: Object to form. Calls for
16 a legal conclusion. Outside the scope.
17 You may answer.
18 THE WITNESS: Yes.
19 BY MR. HONIK:
20 Q. And we looked earlier -- again this
21 foundational -- that among the prohibited acts
22 that the FDA has listed under its regulations
23 under the Food and Drug Act is the sale and
24 placement in the stream of commerce of adulterated
25 drugs. We looked at that together; did we not?

<p style="text-align: right;">Page 142</p> <p>1 MR. DORNER: Same objections. 2 THE WITNESS: Yes. 3 BY MR. HONIK: 4 Q. Now, circling back to where I wanted to 5 be, we looked together in Exhibit 3 Judge Kugler's 6 opinion in the Motion to Dismiss in which he said 7 that regardless whether the sold VCDs actually 8 achieved the medical purpose of lowering blood 9 pressure, it's still considered worthless. 10 Do you remember we looked at that 11 together? 12 MR. DORNER: Are you going to show the 13 witness the document? 14 MR. HONIK: I can if he needs to. 15 BY MR. HONIK: 16 Q. But do you remember that? 17 A. Yes. 18 Q. Okay. Now, if we turn to your paragraph 19 31(a), the criticism that you have here of 20 Dr. Conti is that she didn't take into 21 consideration some potential therapeutic or 22 clinical value of the adulterated VCDs; correct? 23 A. Yes. 24 Q. And in your view as a pharmacist with an 25 MBA, one must take the actual purchase price and</p>	<p style="text-align: right;">Page 144</p> <p>1 of that value that you indicate here is yet to be 2 determined by anybody. But it does have value. 3 BY MR. HONIK: 4 Q. Okay. Well, let's unpack that a little 5 bit. Number one, if the court is correct that 6 even if the adulterated VCDs lowered blood 7 pressure, that is, did what it was supposed to do 8 clinically, if it's still without value, then the 9 full purchase price is the damage; correct? 10 MR. DORNER: Object to the form. 11 Outside the scope. Calls for a legal conclusion. 12 You may answer. 13 THE WITNESS: I'm not an attorney. I 14 don't know the legal answer to that question. 15 BY MR. HONIK: 16 Q. I want you to assume that even if a 17 contaminated drug that works to lower blood 18 pressure and, therefore, creates a clinical value 19 as you suggest in 31(a), that that drug is still 20 worthless. 21 Assuming that statement to be true, the 22 proper measure of damages is the full purchase 23 price of that drug; correct? 24 MR. DORNER: Object to form. Calls for 25 a legal conclusion. Outside the scope.</p>
<p style="text-align: right;">Page 143</p> <p>1 offset it by some calculation for its therapeutic 2 value. That's your point, isn't it? 3 A. Can you repeat that question once more? 4 Q. Sure. Let me rephrase it. 5 Your point in 31(a) is that even if 6 there is some diminution in value to the VCD, that 7 you have to offset whatever that number is by its 8 therapeutic or clinical value to the patient. 9 That's your point, isn't it? 10 MR. DORNER: Object to form. Outside 11 the scope. Mischaracterizes. 12 You may answer. 13 THE WITNESS: Yes. The therapeutic 14 value that the patients receive do have value to 15 them in the healthcare system, yes. 16 BY MR. HONIK: 17 Q. Correct. And according to you, what 18 your model or formula is is that you have to take 19 whatever the purchase or actual price of the drug 20 is and deduct from it the clinical value that the 21 patient received. That's your point; right? 22 MR. DORNER: Same objections. 23 THE WITNESS: I don't think I stated it 24 in that way in my report. Obviously, the 25 therapeutic value, the decision on what percentage</p>	<p style="text-align: right;">Page 145</p> <p>1 You can answer. 2 THE WITNESS: In those hypotheticals and 3 with those requirements, the answer is yes. 4 BY MR. HONIK: 5 Q. And if you're somehow correct, if you 6 were somehow correct as a matter of legal 7 principle, which really controls here, and one 8 must deduct the clinical or therapeutic value, 9 then one must arrive at some value for that 10 clinical benefit; correct? 11 A. Yes. 12 Q. Is it true that you did not present a 13 methodology or formula for evaluating and placing 14 a value on therapeutic benefit? 15 A. That question was outside the scope of 16 my assignment. So, no, I did not calculate that 17 calculation. 18 Q. And, in fact, you have no way of knowing 19 how to do that, do you? 20 A. Well, this is the first time it's been 21 suggested, so I don't know. I haven't thought 22 about it. I would need to consider it and 23 certainly -- 24 Q. How would you in your experience even 25 begin to go about placing a value on the</p>

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1 therapeutic benefits of a drug?
2 MR. DORNER: Object to form. Outside
3 the scope.
4 You can answer.
5 THE WITNESS: Therapeutic benefits to
6 the patient in the healthcare system would be what
7 would the adverse events be if you didn't have
8 that drug and didn't have it replaced by an
9 alternative with similar therapeutic
10 characteristics.
11 Like in this case, you have an ARB that
12 is at issue. It could be an ACE inhibitor. It
13 could be a replacement for that ARB. It could
14 create the value for the patient in lowering the
15 blood pressure.
16 So the first part I would look at would
17 be what is the alternative cost if we don't
18 control this instance. So in this example, if we
19 have antihypertensive patients that have a
20 hypertensive crisis and perhaps they may be
21 subject to a stroke, they might have a heart
22 attack, there are other adverse consequences to
23 not taking their medication. So I would begin to
24 look at what are the costs to the system and to
25 patients for those activities.

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1 And I would venture a guess that the
2 cost of treating an MI or a stroke patient -- that
3 could take months to treat a stroke patient -- is
4 much more expensive than a low cost generic VCD
5 drug. So I would start looking at what would my
6 cost be without those medications as a basis to
7 begin the analysis.
8 You just suggested this, so I haven't
9 thought through other aspects of this, but I'm
10 sure there are other components that would need to
11 be researched, and I'm sure there's data published
12 on what is the average cost of a heart attack, the
13 average cost of a stroke patient. I imagine
14 there's ranges that you could model to estimate
15 what those costs would be if VCD drugs were not
16 taken and the therapeutic benefit was not
17 received.
18 BY MR. HONIK:
19 Q. Suffice to say you didn't do any of that
20 work, did you?
21 A. No. That was not my assignment.
22 Q. Number one. Number two, you're aware,
23 Mr. Kosty, that there were noncontaminated,
24 nonadulterated generic valsartan in the
25 marketplace that the consumer could choose; are

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1 you not?
2 MR. DORNER: Object to characterization.
3 You can answer.
4 THE WITNESS: Well, the pharmacist would
5 choose. The consumer doesn't choose the valsartan
6 drug that's dispensed. It's the pharmacist that
7 would choose. Yeah, the pharmacist would know
8 there were products that didn't have any
9 impurities.
10 BY MR. HONIK:
11 Q. Sir, I'm asking a very simple question.
12 During the relevant class period from 2012 to
13 2018, you were aware, were you not, that apart
14 from the defendants who put contaminated valsartan
15 into the stream of commerce, there were other
16 suppliers who provided uncontaminated valsartan;
17 are you not?
18 MR. DORNER: Object to the
19 characterization.
20 You may answer.
21 THE WITNESS: Yes.
22 BY MR. HONIK:
23 Q. And you were similarly aware that there
24 were other therapies available in the
25 pharmaceutical marketplace to treat high blood

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1 pressure and other coronary ailments; correct?
2 A. Correct.
3 Q. So during the time that consumers and
4 third-party payors were paying for FDA-defined
5 adulterated drugs, there was an option for those
6 entities to purchase drugs that were not
7 adulterated; correct?
8 MR. DORNER: Object to form. Calls for
9 a legal conclusion. Therefore, outside the scope.
10 You may answer.
11 THE WITNESS: Once they were informed
12 there was an issue with the supply of the at-issue
13 VCDs, yes.
14 BY MR. HONIK:
15 Q. And, in fact, that's what happened even
16 after the recall; correct? Consumers were in a
17 position to choose either uncontaminated valsartan
18 or other therapies to control their health
19 conditions; correct?
20 A. Yes, because the at-issue VCD drugs were
21 off the market through a voluntary recall.
22 MR. DORNER: I'll put a late objection
23 to characterization.
24 BY MR. HONIK:
25 [REDACTED]

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1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 BY MR. HONIK:
13 Q. And do you think knowing about the basis
14 for the lack of a sales curve, that is, the
15 legitimacy of uncontaminated drugs in the
16 marketplace would have been relevant to your
17 analysis?
18 MR. DORNER: Objection.
19 Characterization. Outside the scope. Calls for a
20 legal conclusion.
21 You may answer.
22 THE WITNESS: No. I would have -- like
23 I did in my report, from an industry perspective,
24 I would have looked at what was available and what
25 could have been purchased and what, in fact,

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1 happened.
2 Please repeat the question if I didn't
3 answer it. But in my mind, that was the issue.
4 BY MR. HONIK:
5 Q. I understand you. Do you accept as true
6 that a product that doesn't meet cGMP cannot be
7 entered into the legal class of trade in the U.S.
8 pharmaceutical market?
9 MR. DORNER: Object to form. Calls for
10 a legal conclusion. Outside the scope.
11 You may answer.
12 THE WITNESS: From a legal conclusion, I
13 don't know. I would not expect that, but from a
14 legal conclusion, I don't know.
15 BY MR. HONIK:
16 Q. Respectfully, Mr. Kosty, it's not a
17 legal conclusion. It comes from the FDA
18 regulatory scheme.
19 And the question was whether you
20 understood under the FDA's regulatory and
21 enforcement powers that a product that doesn't
22 meet cGMP can't enter the legal class of trade in
23 the U.S. pharmaceutical market. Either you do or
24 you don't.
25 MR. DORNER: Same objections. And lacks

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1 foundation.
2 You can answer.
3 THE WITNESS: Yes.
4 BY MR. HONIK:
5 Q. And in plainer English, that means that
6 pharmacies can't sell products that don't meet
7 cGMP practices and standards nor can a consumer
8 pay for it or their insurance company pay for it.
9 Do you understand that?
10 MR. DORNER: Object to form. Calls for
11 a legal conclusion. Outside the scope.
12 You can answer.
13 THE WITNESS: It depends when that issue
14 is known in the marketplace. If it's known before
15 the product is launched or afterwards and it's
16 recalled, then that product is not available for
17 sale. But, for example, the wholesaler does not
18 test products to determine whether they meet cGMP
19 requirements of the manufacturers.
20 The retailers don't buy product either
21 direct from manufacturers or from wholesalers and
22 test products whether they meet cGMP requirements.
23 So they're depending upon the manufacturer and the
24 FDA to provide that information that they can use
25 in the supply chain.

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1 So if the product was already launched
2 and it was found out that there was issues like
3 there were in this case, products were voluntarily
4 recalled like I would expect to happen in the
5 regulatory framework.
6 If it was before the products were
7 introduced in the market, then those products
8 would not have been available and would not have
9 been launched in the marketplace because the FDA
10 would not have approved those products.
11 BY MR. HONIK:
12 Q. Mr. Kosty, do you agree that the FDA's
13 regulatory scheme requires manufacturers to attest
14 to cGMP compliance not only when first entering
15 the market, but yearly thereafter?
16 MR. DORNER: Object to form. Calls for
17 a legal conclusion. Outside the scope.
18 You may answer.
19 THE WITNESS: My understanding is in
20 this example, the ANDA process, when generics are
21 approved, those attestations are made. And it's
22 my understanding they're reconfirmed on a yearly
23 basis.
24 BY MR. HONIK:
25 Q. And do you agree that the FDA requires

<p style="text-align: right;">Page 154</p> <p>1 not only attestation, that is, a statement, but 2 that you have to produce evidence or proof that 3 you're meeting those cGMP requirements? 4 MR. DORNER: Same objections. Legal 5 conclusion. Outside the scope. 6 THE WITNESS: I don't know. I've never 7 seen those documents to comment on what they 8 include or don't include. 9 BY MR. HONIK: 10 Q. Do you agree that only prescriptions 11 that have met that evidentiary standard for cGMP 12 and are safe and efficacious are allowed to be 13 sold in the U.S. market? 14 MR. DORNER: Same objections. Legal 15 conclusion. Outside the scope. 16 You may answer. 17 THE WITNESS: Yes. Upon approval of 18 their ANDA in this case, yes. 19 BY MR. HONIK: 20 Q. And do you have any knowledge about the 21 economic principle that a drug which doesn't meet 22 those requirements are considered economically 23 worthless and, therefore, have no legitimate 24 supply curve? 25 MR. DORNER: Objection. Lacks</p>	<p style="text-align: right;">Page 156</p> <p>1 periodic inspections of manufacturers to verify 2 their forms that they meet the cGMP requirements. 3 BY MR. HONIK: 4 Q. And, sir, again I understand you're not 5 an economist, but do you understand that there can 6 only be a legitimate supply curve for drugs if and 7 only if a drug is produced in accordance with 8 cGMP, not only by attestation but by empirical 9 proof? 10 MR. DORNER: Object to the form. Lacks 11 foundation. Outside the scope. Calls for a legal 12 conclusion. 13 You can answer. 14 THE WITNESS: The supply curve -- there 15 wouldn't be a supply curve because there wouldn't 16 be a product available in the marketplace in your 17 hypothetical here. 18 BY MR. HONIK: 19 Q. Do you understand that the FDA 20 evidentiary standard for this compliance we've 21 been speaking of concerns not only the cGMP 22 requirements, but evidence of quality, purity, 23 identity and strength of the drug product? 24 MR. DORNER: Object to the 25 characterization. Outside the scope. Calls for a</p>
<p style="text-align: right;">Page 155</p> <p>1 foundation. Outside the scope. 2 You may answer. 3 THE WITNESS: Could you repeat that one 4 more time, please? 5 BY MR. HONIK: 6 Q. Do you agree with the corollary of the 7 last question, namely, that drugs only have an 8 economic value if they meet cGMP and are safe and 9 efficacious? 10 MR. DORNER: Objection. Lacks 11 foundation. Outside the scope. 12 You may answer. 13 THE WITNESS: How do you define economic 14 value? 15 BY MR. HONIK: 16 Q. Do you agree that manufacturers have to 17 attest and prove cGMP compliance and that their 18 drugs are safe and efficacious to sell into the 19 U.S. legal class of trade? 20 MR. DORNER: Object to form. Calls for 21 a legal conclusion. Outside the scope. 22 You may answer. 23 THE WITNESS: They have to attest that 24 their products meet the cGMP requirements, my 25 understanding, and, B, the FDA also conducts</p>	<p style="text-align: right;">Page 157</p> <p>1 legal conclusion. 2 You may answer. 3 THE WITNESS: I'm not a regulatory 4 compliance expert for a pharmaceutical 5 manufacturer, so I don't know specifics what 6 they're required to produce. 7 BY MR. HONIK: 8 Q. Sir, when you got your MBA at Penn 9 State, did you understand there can't be a price 10 given or associated with a product where its 11 demand curve does not meet its supply curve? 12 MR. DORNER: Object to form. Outside 13 the scope. 14 You can answer. 15 THE WITNESS: Yes. 16 BY MR. HONIK: 17 Q. So you understood from that standpoint 18 that if there's no legitimate supply curve which 19 meets that demand curve, no price can be 20 associated with the product in question, 21 correct -- 22 MR. DORNER: Object to form. 23 BY MR. HONIK: 24 Q. -- as a matter of economic principle? 25 MR. DORNER: Object to the form. Lacks</p>

<p style="text-align: right;">Page 158</p> <p>1 foundation. Vague. And outside the scope. 2 You may answer. 3 THE WITNESS: There would be no price 4 because there would be no supply. 5 BY MR. HONIK: 6 Q. Now, in terms of determining the actual 7 purchase price of valsartan-containing drugs as to 8 consumers and TPPs, there is available data that 9 we talked about before the break that would reveal 10 those sums; correct? 11 A. There would be multiple data sources 12 that would have to be referred to to be able to 13 calculate that information. But with the 14 information supplied, you could, yes. 15 Q. And if we could -- do you have a copy of 16 Dr. Conti's report in front of you? 17 A. No, I do not. 18 Q. No problem. 19 MR. HONIK: Dave, can we bring up her 20 report and I'll direct you to a specific part of 21 it. We're going to call this Exhibit 6, I guess. 22 MR. STANOCH: Stand by. 23 THE WITNESS: Okay. 24 (Kosty Exhibit 6 was marked.) 25</p>	<p style="text-align: right;">Page 160</p> <p>1 line? 2 A. I do. 3 Q. The end payor, that's the TPP; right? 4 A. Yes. 5 Q. And the consumer, that's the patient who 6 picked up the prescription; right? 7 A. Yes. 8 Q. And you understood that what Dr. Conti 9 did in arriving at these numbers in this table is 10 she just looked at the actual price paid at the 11 point of sale as between payment from TPPs and 12 payments from consumers. Do you see that? 13 MR. DORNER: Object to the 14 characterization. 15 You can answer. 16 THE WITNESS: Can you point me to where 17 she states that? 18 BY MR. HONIK: 19 Q. So the table doesn't state anything 20 other than the numbers. But having read the 21 report, you understood that the method she 22 employed was to look at IQVIA data of sales at 23 point of sale, and she simply took the actual 24 price. Do you understand that that's what she 25 did?</p>
<p style="text-align: right;">Page 159</p> <p>1 BY MR. HONIK: 2 Q. You've seen this before no doubt, yes? 3 A. Yes. 4 Q. If we turn together to page 31 and look 5 at Table 1 together, this is the table which 6 reflects the Aggregate Manufacturer Group Damages 7 attached to the various theories of liability in 8 this case. Do you remember reviewing this? 9 A. Yes. 10 Q. And you understand because there are 11 multiple theories of legal liability, that there 12 may be an opportunity to add those sums up, but 13 you note in the footnote to this table that 14 they're deduplicated. In other words, they're not 15 added together. 16 Do you understand that concept? 17 MR. DORNER: Object to the 18 characterization. Mr. Kosty didn't note anything 19 in this report. It's not his. 20 THE WITNESS: Yes. 21 BY MR. HONIK: 22 Q. Can you answer my question? 23 A. Yes. 24 Q. So, in other words, just by way of 25 example, if you look at ZHP -- do you see the ZHP</p>	<p style="text-align: right;">Page 161</p> <p>1 A. Yes. 2 Q. And she divided it up between the 3 payment that went from the TPP or insurer and the 4 payment that was collected from the consumer in 5 the form of copays and co-insurances. Do you see 6 that reflected in those numbers? 7 A. Yes. 8 Q. So I understand that you have a 9 different theory and that you've applied this 10 industry sort of approach to it. But assuming the 11 court is correct and assuming we can prove the 12 elements of the Complaint which Dr. Conti assumed, 13 this would be the way you would arrive at the 14 actual cash or purchase price of the drug to 15 determine the damages in a model that looks at the 16 benefit of the bargain theory; correct? 17 MR. DORNER: Object to form. Calls for 18 a legal conclusion. Outside the scope. 19 Mischaracterizes. 20 You can answer. 21 THE WITNESS: The method is partially 22 correct. As I point out in my report, the IQVIA 23 data doesn't identify in approximately 15 percent 24 of the cases who the actual TPP is. And IQVIA is 25 unable to identify those entities. But absent</p>

<p style="text-align: right;">Page 162</p> <p>1 that, the only other information you would have</p> <p>2 would be the data available here.</p> <p>3 BY MR. HONIK:</p> <p>4 Q. Would be the what?</p> <p>5 A. The data here that's available through</p> <p>6 IQVIA.</p> <p>7 Q. Okay. So your criticism of the use of</p> <p>8 the IQVIA data is that you believe there's some</p> <p>9 15 percent that may not be reflected; correct?</p> <p>10 MR. DORNER: Object to form.</p> <p>11 Characterization.</p> <p>12 You can answer.</p> <p>13 THE WITNESS: Yeah. My characterization</p> <p>14 review would be overstated.</p> <p>15 BY MR. HONIK:</p> <p>16 Q. Sir, the methodology that arrived at</p> <p>17 these numbers is correct, save for your criticism</p> <p>18 of the 15 percent that you alluded to in the IQVIA</p> <p>19 data; is that correct?</p> <p>20 MR. DORNER: Object to form. Outside</p> <p>21 the scope. Calls for a legal conclusion.</p> <p>22 You may answer.</p> <p>23 THE WITNESS: That was outside the scope</p> <p>24 of my analysis. But given the IQVIA data, that's</p> <p>25 the only data that would be available to add up</p>	<p style="text-align: right;">Page 164</p> <p>1 MR. DORNER: Object to form.</p> <p>2 Mischaracterization.</p> <p>3 You can answer.</p> <p>4 THE WITNESS: My critique of Dr. Conti's</p> <p>5 analysis is she only did the easy ones. The</p> <p>6 difficult ones are like a Medicare Part D program</p> <p>7 where the government subsidizes approximately 75</p> <p>8 percent of the direct payments to the Med D plan</p> <p>9 which includes the basic -- average national basic</p> <p>10 payment plus a reinsurance payment. The other</p> <p>11 25 percent is paid by the beneficiary through</p> <p>12 premiums.</p> <p>13 So in a Med D plan, the government is</p> <p>14 actually paying 75 percent of the cost of the</p> <p>15 product for the patients. Dr. Conti does not take</p> <p>16 into account those expenditures for these VCD</p> <p>17 prescriptions that are government funded.</p> <p>18 BY MR. HONIK:</p> <p>19 Q. Sir, we're going to ask you a lot of</p> <p>20 questions about Medicare a little later, but when</p> <p>21 you say that she ignores the role of government</p> <p>22 payors, that's false, isn't it? She doesn't</p> <p>23 ignore it, does she?</p> <p>24 A. Not completely, but in certain cases she</p> <p>25 does.</p>
<p style="text-align: right;">Page 163</p> <p>1 here.</p> <p>2 BY MR. HONIK:</p> <p>3 Q. Okay. Fair enough. And if we took this</p> <p>4 and if, as you claim, there should be offsets for</p> <p>5 clinical or therapeutic benefit, you don't know</p> <p>6 and you can't tell us how to arrive at those</p> <p>7 numbers; correct?</p> <p>8 A. That was not part of my assignment, no.</p> <p>9 Q. Do you know of anyone who did that on</p> <p>10 behalf of the defendants?</p> <p>11 MR. DORNER: Object to form. Outside</p> <p>12 the scope. Calls for speculation.</p> <p>13 You can answer.</p> <p>14 THE WITNESS: I don't know.</p> <p>15 BY MR. HONIK:</p> <p>16 Q. Take a look at subparagraph (c) on the</p> <p>17 next page of your report, page 14.</p> <p>18 A. Yes.</p> <p>19 Q. This is the paragraph in which you</p> <p>20 criticized Dr. Conti for ignoring the role of</p> <p>21 government payors. Do you see that?</p> <p>22 A. Yes.</p> <p>23 Q. Do you not remember seeing in her report</p> <p>24 that she specifically excluded government payments</p> <p>25 for these drugs?</p>	<p style="text-align: right;">Page 165</p> <p>1 Q. In fact, if you look at Dr. Conti's</p> <p>2 report at paragraph 75, she states the specific</p> <p>3 ways in which she accounts for government payment,</p> <p>4 doesn't she?</p> <p>5 A. Hold on. Let me get there. That's what</p> <p>6 she states, yes.</p> <p>7 Q. Right. In fact, she's rather specific,</p> <p>8 isn't she? She says that she eliminated CHIP,</p> <p>9 federal assistance programs, Medicare Parts A and</p> <p>10 B, state assistance programs, for example ADAP,</p> <p>11 Tricare, Department of Veterans Affairs, Indian</p> <p>12 Health Service and state employee plans, not</p> <p>13 excluding city and county plans because they're</p> <p>14 private, and workers' compensation.</p> <p>15 Do you see that?</p> <p>16 A. You read that correctly, yes.</p> <p>17 Q. And she footnoted that and said see</p> <p>18 valsartan TPP class definitions and exclusions to</p> <p>19 confirm the fact that she was conforming to the</p> <p>20 class definition and the theories of liability;</p> <p>21 correct?</p> <p>22 MR. DORNER: Object to form.</p> <p>23 Characterization.</p> <p>24 You can answer.</p> <p>25 THE WITNESS: Yes, without seeing that</p>

<p>Page 166</p> <p>1 specific. Could you bring that up and I could 2 take a look at it? 3 BY MR. HONIK: 4 Q. Are you talking about the footnote? 5 A. No, not the footnote. I don't have 6 these class definitions and exclusions memorized. 7 Q. Well, you do because you listed them 8 among your reliance material. They're in the 9 Complaint and Motion for Class Certification. 10 Didn't you read it there? 11 MR. DORNER: Object to form. 12 Argumentative. 13 You can answer. 14 THE WITNESS: I don't have a 15 photographic memory to all the documents I relied 16 upon to recall the specific definition here. 17 BY MR. HONIK: 18 Q. Well, the point here is that, A, she 19 didn't ignore it, and, B, you don't doubt for a 20 second that what she put in or excluded is 21 reflected in the class definition, do you? 22 MR. DORNER: Objection. Object to form. 23 You can answer. 24 THE WITNESS: No, I don't. 25</p>	<p>Page 168</p> <p>1 You can answer. 2 THE WITNESS: The theory of liability 3 was not part of my assignment. I did not look at 4 it. 5 BY MR. HONIK: 6 Q. You didn't consider it at all; right? 7 A. No. 8 MR. DORNER: Object to form. Outside 9 the scope. 10 BY MR. HONIK: 11 Q. So it didn't matter to you whether a 12 particular theory yielding damages sounded in 13 warranty or sounded in unjust enrichment; that 14 difference didn't matter to you, did it? 15 MR. DORNER: Object to form. Outside 16 the scope. 17 You can answer. 18 THE WITNESS: It was outside the scope. 19 It did not. 20 BY MR. HONIK: 21 Q. Sir, do you understand generally that 22 the proper measure of damages at the end of the 23 day will be determined by the court or a court in 24 conjunction with jury findings and not what you 25 think or even I think? Do you understand that?</p>
<p>Page 167</p> <p>1 BY MR. HONIK: 2 Q. Okay. And if you had, if there was some 3 lack of consonance there, you would have raised 4 that in your report and you didn't; right? 5 A. The issues I had were raised in my 6 report, yes. 7 Q. No, no. What I'm asking you is: If 8 there was inconsistency between what Dr. Conti 9 eliminated in the form of government payments, if 10 that was inconsistent with the class definition, 11 you would have pointed that out; would you not? 12 MR. DORNER: Object to form to the 13 extent it calls for a legal conclusion or was 14 outside the scope. 15 You can answer. 16 THE WITNESS: Yes. 17 BY MR. HONIK: 18 Q. And you're familiar -- and you didn't do 19 so; right? 20 A. Didn't do so what? I'm sorry. 21 Q. You didn't point out any inconsistencies 22 between the damage model and the theory of 23 liability, did you? 24 MR. DORNER: Object to form. Outside 25 the scope.</p>	<p>Page 169</p> <p>1 A. Yes. 2 Q. And did you take into consideration any 3 assumptions about what the proper criteria should 4 be for calculating damages in this case? 5 MR. DORNER: Object to form. Outside 6 the scope. 7 You may answer. 8 THE WITNESS: Not from a legal 9 perspective, no. 10 BY MR. HONIK: 11 Q. And it's true that the only perspective, 12 as I understand it, that you applied is something 13 that you referred to as the industry standpoint; 14 right? 15 A. Yes. 16 Q. What exactly do you mean by the industry 17 standpoint? Since if that's the only criteria you 18 used, the court is going to have to evaluate that 19 criteria. What does it mean to look at it from 20 the industry standpoint? 21 A. Well, we have to unpack that a little 22 bit. The industry includes obviously the 23 manufacturers. It includes the wholesalers. It 24 includes the retail pharmacies. So when you look 25 at it from the industry perspective, there's a</p>

<p style="text-align: right;">Page 170</p> <p>1 business model that follows that we all know and 2 are familiar with. I can do a high fly by. 3 But you have the manufacturers that 4 produce the products. You have wholesalers and 5 retailers that buy products from manufacturers. 6 You have retail pharmacies and other types of 7 pharmacies, mail service, specialty, et cetera, 8 that will dispense products to patients. 9 As I note in one of my tables and 10 diagrams in my report, there's a flow of product 11 information, supply information, and there's a 12 flow of pharmacy benefit information in the 13 industry. So when I'm looking at it from an 14 industry perspective, I'm taking both of those 15 flows of product and pharmacy benefit payment flow 16 into account in my opinions. 17 Q. I'm not really sure what you're trying 18 to convey, but are you suggesting that the 19 criteria for measuring damages should be viewed by 20 those that introduced these adulterated drugs into 21 the stream of commerce? 22 MR. DORNER: Object to form. 23 Argumentative. Lacks foundation. 24 THE WITNESS: You mischaracterized my 25 testimony. What I'm explaining to you is how the</p>	<p style="text-align: right;">Page 172</p> <p>1 assignment. 2 BY MR. HONIK: 3 Q. Sir, I'm just asking you what you mean 4 by looking at damages from an industry 5 perspective. How do you take that statement and 6 translate that into a methodology or manner of 7 calculation that the court can evaluate in a 8 Daubert proceeding? 9 MR. DORNER: Object to form. Outside 10 the scope. Calls for a legal conclusion. 11 You may answer. 12 THE WITNESS: That was not my objective 13 or assignment in the report, to calculate -- to 14 develop an economic model of damages. My 15 assignment was to review the expert reports and 16 critique them from an industry perspective. I 17 explained how the flow of product and the flow of 18 pharmacy benefit information happens in the 19 industry. 20 And from an industry perspective, 21 products are sold at a cost from manufacturers to 22 their customers. They're resold in the wholesaler 23 case to the pharmacies. Pharmacies that buy them 24 direct from the manufacturer have a different cost 25 perhaps than the wholesaler cost. So those</p>
<p style="text-align: right;">Page 171</p> <p>1 industry works in practice. 2 BY MR. HONIK: 3 Q. And that's well and good, Mr. Kosty. I 4 get that you understand how that works. I'm 5 asking a rather specific question, and that is -- 6 because you criticized Dr. Conti for how she 7 arrived at damages. And she used legal standards 8 acknowledging she, herself, is not a lawyer 9 because that's how damages get calculated, based 10 on what the court or jury or some combination 11 thereof decides. 12 My question to you is since you didn't 13 do that and you only relied upon an industry's 14 point of view, I'm trying to understand what that 15 point of view is and how it informs the 16 calculation of damages. 17 What is it about the manufacturers, the 18 wholesalers and the retailers informs how to 19 measure damages? 20 MR. DORNER: Object to form. 21 Unintelligible question. Argumentative. Outside 22 the scope. Mischaracterizes. And lacks 23 foundation. 24 You can answer if you can. 25 THE WITNESS: That was not part of my</p>	<p style="text-align: right;">Page 173</p> <p>1 transactions within the industry inform my opinion 2 on what costs are associated with providing those 3 services. 4 So, for example, the wholesalers, in 5 order to provide drugs to pharmacies to dispense 6 to patients, they have to have distribution 7 capabilities. They have to procure product. They 8 likely have over a hundred thousand products in 9 their distribution center to be able to sell to 10 pharmacies for dispensing to patients. So they've 11 incurred a tremendous amount of costs. They have 12 delivery vehicles. They have automation. You 13 name it. There's a lot of costs associated with a 14 wholesaler providing services to their customers. 15 Earlier I explained the cost associated 16 with retailers and their ability to dispense 17 product to patients in terms of purchasing, 18 staffing stores, et cetera. So the revenue flows 19 through. On the other pharmacy side, you have the 20 reimbursement that impacts your revenue, but from 21 the manufacturer and wholesaler and pharmacies, 22 there's a cost of goods sold associated with 23 providing products. 24 From an industry perspective, that's the 25 flow of products through the channels ultimately</p>

<p style="text-align: right;">Page 174</p> <p>1 to patients. That's the perspective I'm taking 2 and that's what I mean from an industry 3 perspective. 4 So when I critique the different 5 analyses, I'm including from the industry 6 perspective. Unlike Dr. Conti, you have to have a 7 product in the pharmacy to be able to sell to a 8 patient. Her assumption is, well, there's no cost 9 associated with the product. In fact, in the 10 industry there is a cost associated with that 11 product. So that's what I'm reflecting in my 12 analysis and differentiating from what she's done. 13 BY MR. HONIK: 14 Q. Mr. Kosty, did you not understand or 15 know that the very letter that you cited as a 16 reliance material was over a discovery battle of 17 whether upstream costs from the retailers and 18 wholesalers could be produced to the plaintiffs in 19 this case? Did you know that? 20 MR. DORNER: Object to form. The 21 characterization. 22 THE WITNESS: I did not. 23 BY MR. HONIK: 24 Q. Even though you read the letter and 25 cited it in the Appendix C as a reliance material;</p>	<p style="text-align: right;">Page 176</p> <p>1 A. Yes. 2 Q. And do you remember we discussed -- 3 let's back up. Among all the letters, countless 4 letters sent into the court in this case and 5 various things on the docket, you listed this as a 6 reliance material; right? 7 A. Yes. 8 Q. And as I understood it, the reason you 9 told me you did that was because of some 10 confidentiality that attached to this upstream 11 data that the retailers and wholesalers didn't 12 want to produce; right? 13 A. Yeah, specific to the pharmacy, yes, to 14 pharmacy benefit agreements, yes. 15 Q. So here's my question: Are you aware 16 sitting here today that no upstream cost data was 17 ever provided to the plaintiffs in this case? 18 MR. DORNER: Object to form. Outside 19 the scope. Mischaracterizes. 20 You can answer. 21 THE WITNESS: Yes. I am aware of that. 22 BY MR. HONIK: 23 Q. And you're aware, or maybe you're not, 24 that unjust enrichment requires looking at a 25 formula that requires calculating profit; correct?</p>
<p style="text-align: right;">Page 175</p> <p>1 correct? 2 MR. DORNER: Same objections. 3 Argumentative. 4 You can answer. 5 THE WITNESS: Could you refer me to that 6 specific letter you're mentioning, the one you 7 showed earlier? 8 BY MR. HONIK: 9 Q. Sure. It's been marked as an exhibit, 10 and you specifically relied on it or I should say 11 more accurately, the defense lawyers provided it 12 to you. 13 MR. DORNER: Object to the 14 characterization. There's no question either. 15 THE WITNESS: What exhibit was that? 16 MR. HONIK: Dave, do you remember the 17 number? 18 MR. STANOCH: Two. 19 BY MR. HONIK: 20 Q. It's Exhibit 2, sir. 21 MR. DORNER: Is there a question 22 pending? 23 MR. HONIK: Yeah. 24 BY MR. HONIK: 25 Q. Do you remember looking at that exhibit?</p>	<p style="text-align: right;">Page 177</p> <p>1 MR. DORNER: Object to form. Calls for 2 a legal conclusion. Outside the scope. 3 You may answer. 4 THE WITNESS: I'm not familiar with the 5 unjust enrichment formula from a legal 6 perspective, no. 7 BY MR. HONIK: 8 Q. Well, that's curious because one of your 9 most substantial criticisms is that profit isn't 10 properly calculated by Dr. Conti because she 11 didn't take into consideration costs. 12 Isn't that one of your criticisms? 13 A. Yes. 14 Q. And my only question you to is: Were 15 you aware that we sought the identity of those 16 costs and they were not produced at least to this 17 point? Are you aware of that? 18 MS. KAPKE: Object to form. 19 Mischaracterizes the record to date. 20 MR. DORNER: We'll join in that. 21 BY MR. HONIK: 22 Q. Mr. Kosty, you can answer. 23 A. Yes. I'm aware that information has not 24 been produced. 25 Q. We have sales data. We have point of</p>

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1 purchase data. But we have no upstream costs
 2 provided to us. Do you know that?
 3 MR. DORNER: Same objections.
 4 THE WITNESS: Yes.
 5 BY MR. HONIK:
 6 Q. And are you aware having reviewed at
 7 least some parts of Dr. Conti's testimony and all
 8 of her report that she said if we're produced that
 9 information, that can be easily and flexibly
 10 worked into her methodology for calculating
 11 damages? Are you aware of that?
 12 MR. DORNER: Same objection.
 13 Mischaracterizes. Outside the scope.
 14 You can answer.
 15 THE WITNESS: Yes.
 16 BY MR. HONIK:
 17 Q. I'm sorry. Did you say "yes"?
 18 A. Yes.
 19 Q. And you did not design or certainly in
 20 your report there's no evidence that you designed
 21 a methodology or formula for calculating the costs
 22 that you complained that Dr. Conti didn't
 23 consider; right?
 24 MR. DORNER: Outside the scope.
 25 You can answer.

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1 THE WITNESS: That was not my
 2 assignment, so I did not do that.
 3 BY MR. HONIK:
 4 Q. Understood. You didn't do it because
 5 nobody asked you to do it; right?
 6 A. Correct.
 7 Q. Now, in your assignment in Loestrin, did
 8 you use the same methodology, that is, look at
 9 damages from the standpoint of industry much as
 10 you did here?
 11 MR. DORNER: Mr. Kosty, in response to
 12 this question, I'll just caution you to the extent
 13 there's any of confidentiality orders in place
 14 that prohibits you, to avoid violating any of
 15 those provisions.
 16 THE WITNESS: I don't recall.
 17 BY MR. HONIK:
 18 Q. What did you do in Loestrin?
 19 MR. DORNER: Same instruction,
 20 Mr. Kosty.
 21 THE WITNESS: At a high level, I
 22 reviewed the case documentation, produced an
 23 expert report and testified via deposition.
 24 BY MR. HONIK:
 25 Q. So that involved the drug Loestrin and

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1 the fact that there was cGMP violations from the
 2 facility from which it was manufactured; correct?
 3 MR. DORNER: Object to form.
 4 You can answer.
 5 THE WITNESS: I don't recall the
 6 specifics, no.
 7 BY MR. HONIK:
 8 Q. Do you recall any of the specifics?
 9 A. Not to that level of detail, no. I'm
 10 not sure how many years ago, three or four years
 11 ago. I've had probably hundreds of projects since
 12 that time. I haven't looked at that
 13 documentation. No, I don't recall.
 14 Q. That's somewhat astonishing to me
 15 because for all of your projects in the industry,
 16 you've only had in the last four years four legal
 17 matters. Am I wrong about that?
 18 MR. DORNER: Object to form.
 19 Argumentative.
 20 You can answer.
 21 THE WITNESS: You mischaracterized our
 22 business. Like I mentioned to you earlier in this
 23 deposition, our focus is not on legal cases. Our
 24 focus is on working with our clients in different
 25 market segments on their business problems.

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1 BY MR. HONIK:
 2 Q. That's precisely my point.
 3 MR. DORNER: I'm sorry. Mr. Honik, the
 4 witness was not finished.
 5 THE WITNESS: Thank you.
 6 So the focus of our consulting practice
 7 is not legal cases. The focus of our consulting
 8 practice is on consulting in the industry. And
 9 along the line of doing hundreds of projects over
 10 the years with multiple segments of the industry,
 11 we understand, I understand how the industry
 12 works, how the interrelationships between all the
 13 different parties work from a contractual
 14 perspective, from an operational perspective, and
 15 from a financial perspective.
 16 So that's been the focus of our
 17 consulting business. It's not been a focus to be
 18 a professional witness.
 19 BY MR. HONIK:
 20 Q. You have billed something on the order
 21 of magnitude -- Mr. Stanoch will review it with
 22 you -- about \$600,000 in this case; right?
 23 MR. DORNER: Objection. If you're going
 24 to refer to invoices and Mr. Stanoch will go over
 25 them, I'd ask that he at least be shown the

<p style="text-align: right;">Page 182</p> <p>1 documents you're referencing. 2 BY MR. HONIK: 3 Q. Am I wrong? You made about \$600,000 in 4 this case? 5 MR. DORNER: Object to the 6 characterization. 7 THE WITNESS: I do not know how much our 8 company has made. I haven't made money 9 personally. Our company is paid for my services. 10 BY MR. HONIK: 11 Q. AG billed for your work and their work 12 collectively about 600 grand; right? 13 A. I don't know. I haven't added up the 14 invoice. It was not important to me. 15 Q. It strikes me, Mr. Kosty, that the very 16 point you're making, that your ordinary work in 17 the pharmacy industry is the vast bulk of what you 18 do, that your work in this legal arena, few cases 19 as there have been, do not stand out in your mind 20 such that you don't know anything about Loestrin; 21 right? 22 MR. DORNER: Objection. Counsel is 23 testifying. Argumentative. 24 You can answer if there is a question. 25 THE WITNESS: I don't know what the</p>	<p style="text-align: right;">Page 184</p> <p>1 no. 2 BY MR. HONIK: 3 Q. You recall giving testimony, don't you? 4 A. I recall a deposition, yes. I don't 5 recall specifically what I said during that 6 testimony if you're going to ask me questions 7 about that, sir. 8 Q. Well, in preparation for today's 9 testimony, you reviewed your Loestrin testimony, 10 didn't you? 11 A. I did not. 12 Q. Did you have a discussion about your 13 involvement in Loestrin? Yes or no. 14 A. Discussion with whom? 15 Q. I don't know what you said. Did you 16 talk to anybody in preparation for today about the 17 work you previously did in the Loestrin matter? 18 A. No. 19 MR. DORNER: Objection to the extent 20 it's seeking conversations with counsel. They're 21 protected by work product. 22 BY MR. HONIK: 23 Q. You're aware, are you not -- 24 MR. DORNER: Sorry. Mr. Honik, I wasn't 25 finished with my objection, and the court reporter</p>
<p style="text-align: right;">Page 183</p> <p>1 question is, but you mischaracterize. There was 2 no need for me to look at -- 3 BY MR. HONIK: 4 Q. What work did you do in Loestrin? What 5 work did you do in Loestrin? 6 MR. DORNER: Objection. Asked and 7 answered. I would caution the witness not to 8 divulge anything subject to a confidentiality 9 order or privilege. 10 THE WITNESS: I would have to consult 11 with counsel before getting into specifics. 12 BY MR. HONIK: 13 Q. Did you do work that was similar in 14 nature to the work you were asked to do here? 15 MR. DORNER: Same instruction. You're 16 trying to back door it, Mr. Honik. I can't allow 17 that and allow the witness to get in trouble. 18 THE WITNESS: On the advice of counsel, 19 I'm not going to answer that question. 20 BY MR. HONIK: 21 Q. Did you do work in Loestrin pertaining 22 to damages and ascertainability? 23 MR. DORNER: Same -- if you can answer 24 it, that's fine. 25 THE WITNESS: I don't recall specifics,</p>	<p style="text-align: right;">Page 185</p> <p>1 needs a break here. Object to the extent it's 2 calling for work product and the impressions of 3 counsel. Next question. 4 BY MR. HONIK: 5 Q. You're aware that there was a motion to 6 exclude your testimony in that case; correct? 7 A. That's my understanding, that that's a 8 motion made for all experts. 9 Q. Whether it was or not, you're aware of 10 there was one made for you; right? 11 A. Yes. 12 Q. And when that occurred, that was shared 13 with you so that you could consult with the 14 attorneys in defending your opinions; did you not? 15 MR. DORNER: Objection. Again, don't 16 answer anything respecting conversations that you 17 had with counsel for the purpose providing an 18 expert opinion in another case potentially also 19 protected by a confidentiality order. 20 THE WITNESS: On the advice of counsel, 21 I'm not going to answer that question. 22 BY MR. HONIK: 23 Q. You're not being advised not to answer 24 it. You're being advised not to reveal certain 25 information if it's subject to the</p>

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1 confidentiality. Otherwise, you can respond.
2 A. It's subject to confidentiality.
3 Q. I beg your pardon?
4 A. I don't have approval from the attorneys
5 in that case to discuss anything. Like I
6 mentioned to you, I haven't reviewed those
7 documents. So I don't recall specifics to any of
8 those motions, et cetera.
9 Q. Do you remember the question I asked?
10 A. Yes. You asked if I had reviewed the
11 opinion -- I think it's called a Daubert motion,
12 is that correct -- to exclude my testimony.
13 Q. I asked you if you were aware that there
14 was a motion to exclude your specific testimony.
15 A. Yes.
16 Q. And do you recall discussing that motion
17 and the basis with counsel? Yes or no. I don't
18 want to know what was said.
19 A. No.
20 Q. You don't recall --
21 A. No.
22 Q. -- speaking to counsel about it?
23 A. No. I don't recall.
24 Q. Do you remember that you, yourself, read
25 the motion and the basis for challenging your

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1 opinions?
2 A. I did read the motion.
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]
25 [REDACTED]

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[REDACTED]

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[REDACTED]

19 BY MR. HONIK:
20 Q. Mr. Kosty, are you aware that the
21 defense lawyers in the Loestrin case, in fact,
22 dedesignated much of your testimony as not
23 confidential?
24 MR. DORNER: Objection.
25 Mischaracterizes. Lacks foundation. Same

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1 instruction.

2 MR. HONIK: How do you know that that is

3 a mischaracterization? Are you attesting to the

4 fact that it's confidential, his testimony?

5 MR. DORNER: I'm not attesting to

6 anything, and I haven't said that, Mr. Honik.

7 MR. HONIK: Then don't instruct your

8 client not to answer because we're just going to

9 come back here.

10 MR. DORNER: The instruction is to not

11 answer with anything that is covered by a

12 confidentiality order.

13 BY MR. HONIK:

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 [REDACTED]

20 [REDACTED]

21 [REDACTED]

22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

25 [REDACTED]

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1 [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 BY MR. HONIK:

13 Q. You're able to get an answer by review

14 of your own testimony, a transcript of which you

15 possess; correct?

16 A. I could review my testimony, but I would

17 need to contact the attorneys we worked with in

18 this case, in the Loestrin case, to get any

19 clearance from them. I don't have clearance to

20 share documentation.

21 Q. Let me ask you this before I move on:

22 Apart from that potential obstacle which I

23 maintain doesn't exist, do you, nonetheless, have

24 recall sufficient to answer my question now?

25 A. I don't.

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1 [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 instructing you not to answer anything subject to

7 a confidentiality order. Asked and answered a

8 ridiculous amount of times. Calls for a legal

9 conclusion. Outside the scope. Lacks foundation.

10 Argumentative.

11 Move on, counsel.

12 MR. HONIK: Mr. Dorner, do you know

13 Shakespeare?

14 MR. DORNER: I'm not testifying here

15 today, Ruben.

16 MR. HONIK: Do you know the phrase,

17 "Methinks she doth protest too much"? You may

18 want to stop while you're ahead.

19 BY MR. HONIK:

20 Q. Do you remember the question, Mr. Kosty?

21 A. No, I don't.

22 Q. The question was: Do you have

23 sufficient memory today sitting there under oath

24 to at least remember that the basis for trying to

25 exclude your testimony was that the central

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1 premise of your opinion was false? Do you

2 remember that that was raised?

3 MR. DORNER: Same objections.

4 You can answer.

5 THE WITNESS: No, I don't.

6 BY MR. HONIK:

7 Q. Do you know that the court did not rule

8 on your exclusion because the case was certified

9 and then settled? Do you know that much?

10 MR. DORNER: Objection. Outside the

11 scope. Calls for a legal conclusion. Lacks

12 foundation.

13 You may answer.

14 THE WITNESS: I do know the case was

15 settled. That's the extent to it.

16 BY MR. HONIK:

17 Q. And in your memory, how long ago did

18 this occur?

19 MR. DORNER: Objection as to whatever

20 "this" is.

21 THE WITNESS: Yeah, what is "this"?

22 What do you speak of?

23 BY MR. HONIK:

24 Q. If I said to you that the motion to

25 exclude your testimony was filed in February of

<p>Page 194</p> <p>1 2019, would that comport with your memory?</p> <p>2 A. Yes, because it was before COVID. I</p> <p>3 always look at things pre- and post-COVID, right.</p> <p>4 Q. It was only in 2019; correct?</p> <p>5 A. Yes.</p> <p>6 Q. And you have no memory that would allow</p> <p>7 you to respond to any of my questions?</p> <p>8 A. That's correct. No memory to those</p> <p>9 specifics that you obviously want to get into. I</p> <p>10 don't recall. I haven't looked at that</p> <p>11 documentation since 2019.</p> <p>12 Q. You're aware that there was an in-person</p> <p>13 or in-court class certification hearing in</p> <p>14 Loestrin?</p> <p>15 A. Yes.</p> <p>16 Q. Did you say "yes"?</p> <p>17 A. Yes.</p> <p>18 Q. And you're aware that every single one</p> <p>19 of the defense experts got to testify, but you</p> <p>20 didn't; right?</p> <p>21 A. I wasn't aware of that. I know I didn't</p> <p>22 testify. I was there available to testify.</p> <p>23 Q. I'm sorry. I spoke over you, and I</p> <p>24 apologize. What was the last thing you said?</p> <p>25 A. I was there available to testify and I</p>	<p>Page 196</p> <p>1 rebate payments under their supply agreement that</p> <p>2 was the subject of a creditor action to recoup</p> <p>3 those payments, right, into the bankruptcy estate?</p> <p>4 A. That's incorrect.</p> <p>5 Q. Okay. What was involved if not that?</p> <p>6 A. I don't have approval from counsel to</p> <p>7 discuss this matter.</p> <p>8 Q. What can you tell me that you did and</p> <p>9 your assignment was in that matter?</p> <p>10 A. I don't have approval from counsel to</p> <p>11 discuss this matter.</p> <p>12 Q. On what basis do you believe it's</p> <p>13 subject to a confidentiality or other protective</p> <p>14 order?</p> <p>15 MR. DORNER: Object to form. Calls for</p> <p>16 a legal conclusion.</p> <p>17 You can answer.</p> <p>18 THE WITNESS: My experience with legal</p> <p>19 cases, if anything that needs to be disclosed, it</p> <p>20 needs to be discussed with the attorneys ahead of</p> <p>21 time and get proper clearances. And my</p> <p>22 understanding is any of these questions that come</p> <p>23 up, I need to consult with counsel for McKesson in</p> <p>24 this case.</p> <p>25</p>
<p>Page 195</p> <p>1 wasn't called upon.</p> <p>2 Q. Well, in fact, the defense lawyers told</p> <p>3 you that they weren't going to call you; isn't</p> <p>4 that right?</p> <p>5 MR. DORNER: Don't answer that question.</p> <p>6 THE WITNESS: On the advice of counsel,</p> <p>7 I'm not going to answer that question.</p> <p>8 BY MR. HONIK:</p> <p>9 Q. Sir, the fact remains that you didn't</p> <p>10 testify at the class certification hearing. Do</p> <p>11 you know why?</p> <p>12 MR. DORNER: Don't answer that question</p> <p>13 to the extent -- don't answer the question.</p> <p>14 MR. HONIK: You're instructing him not</p> <p>15 to answer why he understands he didn't testify?</p> <p>16 MR. DORNER: Yes, I am. Move on.</p> <p>17 BY MR. HONIK:</p> <p>18 Q. You testified in the A&P bankruptcy</p> <p>19 case, didn't you?</p> <p>20 A. Yes. I produced a report and took a</p> <p>21 deposition.</p> <p>22 Q. And in that case I think you were an</p> <p>23 expert for McKesson; right?</p> <p>24 A. Correct.</p> <p>25 Q. And that case involved significant</p>	<p>Page 197</p> <p>1 BY MR. HONIK:</p> <p>2 Q. So you didn't do that in advance of</p> <p>3 today. And you don't know sitting here if you are</p> <p>4 prohibited or not; right?</p> <p>5 A. I'm not an attorney, but in an abundance</p> <p>6 of caution, I will request that I need to consult</p> <p>7 with counsel in that case before making any</p> <p>8 statements.</p> <p>9 Q. You didn't do that before today, did</p> <p>10 you?</p> <p>11 A. No.</p> <p>12 Q. What did you do in the confidential</p> <p>13 arbitration related to pharmacy claims that you</p> <p>14 listed?</p> <p>15 A. I know that one is confidential because</p> <p>16 I asked the counsel proactively about that case.</p> <p>17 Q. I'm sorry. I'm sorry. You said it's</p> <p>18 not confidential?</p> <p>19 A. I said it is confidential.</p> <p>20 Q. Let me understand your testimony. Did</p> <p>21 you just tell me that before today, you checked</p> <p>22 with counsel on that one?</p> <p>23 A. Yes.</p> <p>24 Q. And you did so in anticipation that you</p> <p>25 might be asked questions about it today?</p>

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1 A. I did it in anticipation of what could
 2 be disclosed in my report. So if you look at the
 3 exhibit in my report, it's very high level, right?
 4 Would you agree?
 5 Q. I don't know what you're talking about.
 6 What exhibit?
 7 A. Appendix B. I'm sorry.
 8 Q. I'm looking at Appendix B in which you
 9 list --
 10 A. Confidential --
 11 Q. Let me ask the question. Are you
 12 referring to Appendix B in which you list the only
 13 four expert testimonies in the past four years?
 14 A. Yes, and specifically to number two.
 15 Q. Right. And what you're telling me is
 16 that in advance of today, you took the time to
 17 check with counsel in item number two, this
 18 arbitration-related matter, to learn whether or
 19 not it was confidential, and you told me that it
 20 is. Isn't that what you said?
 21 MR. DORNER: Object to the
 22 characterization.
 23 You can answer.
 24 THE WITNESS: Yeah, that
 25 mischaracterizes the statement there. The reason

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1 I checked with counsel was to get an update on the
 2 status of the case. And, oh, by the way, counsel,
 3 I'm involved with another legal matter. How is
 4 this considered? Is there anything I can state
 5 about this if questioned, and the answer was no.
 6 BY MR. HONIK:
 7 Q. Wait, wait. Let me understand what
 8 you're telling me. The item at number two, the
 9 legal matter there, that's still pending?
 10 A. It's been settled is my understanding.
 11 I haven't seen any documentation, but counsel said
 12 it was settled.
 13 Q. And number three is settled and number
 14 four is settled; right?
 15 A. I do not know about number three. I
 16 don't know the status of that case.
 17 Q. But you told me under oath that you
 18 reached out to the lawyers in matter number two,
 19 the confidential arbitration, to find out the
 20 status, but it was already settled; right?
 21 A. It was in the process of being settled
 22 was what was told to me by counsel.
 23 MR. DORNER: And, again, I have to
 24 instruct don't go on anything that you're not
 25 allowed to say pursuant to confidentiality.

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1 BY MR. HONIK:
 2 Q. Why didn't you do the same exact thing
 3 for the Loestrin matter and the A&P matter? Why
 4 didn't you call the lawyers there in advance of
 5 today and check on the status and whether you
 6 were, as Mr. Dorner seems to suggest, prohibited
 7 from revealing information to us?
 8 MR. DORNER: Object to form.
 9 Argumentative.
 10 You can answer.
 11 THE WITNESS: It was not part of my
 12 preparation for this case. I mean, you wanted a
 13 listing of the ones I've submitted expert reports.
 14 That's what I provided. It wasn't -- like I said,
 15 it wasn't my point to go and ask these people for
 16 permission or not to testify about it. My
 17 understanding of this process today, you were
 18 going to ask me about my report in this case.
 19 BY MR. HONIK:
 20 Q. Sir, you did tell me that you did call
 21 the lawyers in item number two to find out if it
 22 was subject to confidentiality. That's what you
 23 told me.
 24 And my question is -- let me finish the
 25 question -- why didn't you do the very same thing

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1 in the two other matters involving McKesson and
 2 Loestrin?
 3 MR. DORNER: Object to form.
 4 Mischaracterizes. Argumentative.
 5 You may answer.
 6 THE WITNESS: I reached out to counsel
 7 to see if I could provide a description of the
 8 case to include in Appendix B. Counsel informed
 9 me, no, we do not want you to provide that
 10 information. It's confidential. So on advice of
 11 counsel, that's what I've done. And number two is
 12 read that way.
 13 BY MR. HONIK:
 14 Q. I understand that completely, Mr. Kosty.
 15 And my question is: Why didn't you do the very
 16 same thing as to item three, the A&P/McKesson
 17 matter, and number four, the Loestrin matter in
 18 which your testimony was sought to be excluded?
 19 Why didn't you check on those two?
 20 MR. DORNER: Same objection plus asked
 21 and answered multiple times.
 22 THE WITNESS: Those cases -- obviously
 23 Loestrin settled. The A&P, I don't know the
 24 status of that case. There was no reason to reach
 25 out for an update. So I didn't.

<p style="text-align: right;">Page 202</p> <p>1 BY MR. HONIK:</p> <p>2 Q. What I'm asking you is why didn't you</p> <p>3 learn in advance of today --</p> <p>4 A. I just answered your question. There</p> <p>5 was no reason.</p> <p>6 Q. Let me finish the question, sir. Let me</p> <p>7 finish.</p> <p>8 Why didn't you do as to the McKesson and</p> <p>9 Loestrin matters the same as you did in the</p> <p>10 arbitration and learn whether you were subject to</p> <p>11 some confidentiality or other privilege obstacle?</p> <p>12 Why didn't you do that?</p> <p>13 MR. DORNER: I have to stop you, but not</p> <p>14 because of an objection. You cut out in the</p> <p>15 middle of your question, Ruben. I'm sorry, but</p> <p>16 could you repeat it?</p> <p>17 MR. HONIK: Ann, did you get it?</p> <p>18 COURT REPORTER: I think I did.</p> <p>19 MR. DORNER: I missed about four words</p> <p>20 in the middle.</p> <p>21 (The following record was read back:</p> <p>22 "Q Why didn't you do as to the</p> <p>23 McKesson and Loestrin matters the same as you</p> <p>24 did in the arbitration and learn whether you</p> <p>25 were subject to some confidentiality or other</p>	<p style="text-align: right;">Page 204</p> <p>1 you did?</p> <p>2 A. I submitted an expert report in the</p> <p>3 case, and no deposition was taken.</p> <p>4 Q. That was a case concerning Actos; right?</p> <p>5 And that was a RICO claim. Do you remember that?</p> <p>6 A. Yes.</p> <p>7 Q. And that was brought by TPPs and end</p> <p>8 users as well; right?</p> <p>9 A. I don't recall the specifics.</p> <p>10 Q. Well, did you prepare a report or submit</p> <p>11 a report, as you state here, on the issues of</p> <p>12 damages and ascertainability?</p> <p>13 A. As previously answered, I will have to</p> <p>14 consult with the counsel for that case before</p> <p>15 answering that question.</p> <p>16 Q. I'm just asking the topics on which</p> <p>17 you --</p> <p>18 A. I'm unwilling to provide those topics to</p> <p>19 you.</p> <p>20 Q. Do you know sitting here what the topics</p> <p>21 are and you're just not going to tell me because</p> <p>22 you might be subject to a confidentiality? Just</p> <p>23 tell me that.</p> <p>24 A. Yes.</p> <p>25 Q. Okay. So you do know the topics that</p>
<p style="text-align: right;">Page 203</p> <p>1 privilege obstacle? Why didn't you do</p> <p>2 that?")</p> <p>3 THE WITNESS: Because I didn't need an</p> <p>4 update on those cases.</p> <p>5 BY MR. HONIK:</p> <p>6 Q. Did you check with the lawyers in the</p> <p>7 Takeda matter about whether you could testify</p> <p>8 about your role in that case?</p> <p>9 A. I did not.</p> <p>10 Q. Do you know whether or not there's any</p> <p>11 prohibition against your revealing what you did in</p> <p>12 that case?</p> <p>13 A. I don't, but I would ask them before</p> <p>14 providing any information on that case.</p> <p>15 Q. And who engaged you in that matter?</p> <p>16 A. That's another case with the Analysis</p> <p>17 Group.</p> <p>18 Q. I didn't quite catch the end of your</p> <p>19 answer.</p> <p>20 A. Who engaged me? The attorneys engaged</p> <p>21 me in that case through the Analysis Group.</p> <p>22 Q. And what work did you do?</p> <p>23 A. I will need to get their approval before</p> <p>24 sharing that information.</p> <p>25 Q. You can't even tell me what kind of work</p>	<p style="text-align: right;">Page 205</p> <p>1 you prepared your report in Takeda; right?</p> <p>2 A. Yes.</p> <p>3 Q. And you do know the subjects of your</p> <p>4 submitted expert report in the arbitration;</p> <p>5 correct?</p> <p>6 A. Yes.</p> <p>7 Q. And you do know the topics in which you</p> <p>8 prepared a report and gave deposition testimony in</p> <p>9 the A&P bankruptcy case; right?</p> <p>10 A. Yes.</p> <p>11 Q. And we've already -- well, perhaps we</p> <p>12 haven't. Can you tell me the subjects of your</p> <p>13 report in Loestrin?</p> <p>14 MR. DORNER: Same instruction with</p> <p>15 respect to confidentiality and privilege.</p> <p>16 THE WITNESS: I'm going to have to</p> <p>17 consult with counsel before answering those</p> <p>18 questions.</p> <p>19 BY MR. HONIK:</p> <p>20 Q. Do you know sitting here today whether</p> <p>21 or not the topics of your expert report in</p> <p>22 Loestrin are the same topics as those on which</p> <p>23 you've given a report in this case?</p> <p>24 MR. DORNER: Same instructions. It's</p> <p>25 just a back door.</p>

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1 THE WITNESS: Yeah, I'm going to have to
2 ask counsel before disclosing any information.

³ BY MR. HONIK:

4 Q. I'm simply asking if they're the same or
5 different topics.

6 A. I don't recall.

7 Q. You don't recall the topics on which you
8 gave testimony and prepared a report in Loestrin,
9 is that your sworn testimony?

10 MR. DORNER: Same instruction.

11 THE WITNESS: I'm going to have to
12 consult with counsel before answering.

13 BY MR. HONIK:

14 Q. Listen to what I'm asking, Mr. Kosty.
15 Sitting here today, is it your testimony that you
16 do not know in your head, putting aside any
17 confidentiality, that you simply do not know the
18 topics on which you gave testimony and prepared a
19 report in Loestrin?

20 A. I do know the topics, but I don't know
21 the specifics.

22 Q. That's right. And the follow-up and
23 final question is: Are those topics the same or
24 different topics than those in which you wrote in
25 this case?

1 MR. DORNER: Do not answer that question
2 to the extent it requires you to divulge
3 confidential information.

4 MR. HONIK: In what way would that be
5 subject to any confidentiality impediment?

6 MR. DORNER: Mr. Honik, your experts
7 have marked their reports as Restricted

8 Confidential, which means they can be disclosed
9 for other purposes. If Mr. Kosty's report is
10 likewise marked that way in the Loestrin matter, a
11 point which I don't know --

12 MR. HONIK: I don't know what you're
13 talking about.

14 MR. DORNER: I'm answering your
15 question, Mr. Honik.

16 MR. HONIK: I'm only asking if the
17 topics are the same or different. That's the
18 question that's pending.

19 MR. DORNER: Do not answer.

20 BY MR. HONIK:

21 Q. Are the topics in Loestrin the same or
22 different than the ones you wrote on here? That's
23 all. Can you answer that question?

24 MR. DORNER: If he answers yes, then you
25 can back door exactly what was said in Loestrin.

17 A. Yes, I can.

18 O. Can you hear me?

19 A. Loud and clear.

20 Q. Very good, sir. You understand you're
21 still under oath; right?

22 A. Yes.

23 Q. I'd like to focus on your opinions
24 regarding Ms. Craft and what courts call
25 ascertainability. Okay?

<p style="text-align: right;">Page 210</p> <p>1 A. Yes.</p> <p>2 Q. And you understand you offer some</p> <p>3 opinions in this case in that regard; right?</p> <p>4 A. Right.</p> <p>5 Q. And, for instance, if we look at</p> <p>6 paragraph 30 of your report, you summarize your</p> <p>7 opinions with respect to the identification of</p> <p>8 class members; correct?</p> <p>9 A. Let me get there real quick. Paragraph</p> <p>10 30 did you say?</p> <p>11 Q. Let me know when you're there.</p> <p>12 A. Yes. Okay.</p> <p>13 Q. You're there, sir?</p> <p>14 A. I am there.</p> <p>15 Q. Great. And is it correct that this</p> <p>16 paragraph and its subsections is your summary of</p> <p>17 opinions relating to identification of class</p> <p>18 members?</p> <p>19 A. Yes.</p> <p>20 Q. And you have five subparts there, (a)</p> <p>21 through (e); is that right?</p> <p>22 A. That's correct.</p> <p>23 Q. Subpart (a) talks about identifying the</p> <p>24 final TPP payor for prescription drugs; right?</p> <p>25 A. Yes.</p>	<p style="text-align: right;">Page 212</p> <p>1 the proposed medical monitoring classes; correct?</p> <p>2 A. That's correct.</p> <p>3 Q. This critique does not relate to the</p> <p>4 proposed TPP or economic loss consumer classes;</p> <p>5 right?</p> <p>6 A. Correct.</p> <p>7 Q. And then subpart (c), you talk about</p> <p>8 exclusions; correct?</p> <p>9 A. Yes.</p> <p>10 Q. You give the example of state government</p> <p>11 entities; correct?</p> <p>12 A. Correct.</p> <p>13 Q. Which classes does this critique relate</p> <p>14 to?</p> <p>15 A. The TPP class.</p> <p>16 Q. Right. So the paragraph 30(c) relates</p> <p>17 to the proposed TPP class only; right?</p> <p>18 A. Correct.</p> <p>19 Q. And then subpart (d) of paragraph 30</p> <p>20 talks about lot number information and expiration</p> <p>21 date; is that correct?</p> <p>22 A. That's correct.</p> <p>23 Q. And these critiques as set forth in</p> <p>24 paragraph 30(d) relate to the medical monitoring</p> <p>25 class; correct?</p>
<p style="text-align: right;">Page 211</p> <p>1 Q. So this subsection relates to the</p> <p>2 proposed third-party payor or TPP class; correct?</p> <p>3 A. Correct.</p> <p>4 Q. And actually, before we keep going, we</p> <p>5 can agree, can we not, that there's three proposed</p> <p>6 classes here; correct? There's the economic loss</p> <p>7 consumer class, the economic loss TPP class, and</p> <p>8 the medical monitoring class; right?</p> <p>9 A. Yes.</p> <p>10 Q. So we can speak generally about those</p> <p>11 three overarching buckets of proposed classes; is</p> <p>12 that fair?</p> <p>13 A. Thank you.</p> <p>14 Q. So as you said, subpart (a) of your</p> <p>15 paragraph 30 relates to the proposed TPP class;</p> <p>16 correct?</p> <p>17 A. Correct.</p> <p>18 Q. This critique of yours has nothing to do</p> <p>19 with the economic loss consumer class or the</p> <p>20 medical monitoring class; correct?</p> <p>21 A. That's correct.</p> <p>22 Q. The next subpart you have is 30(b);</p> <p>23 right?</p> <p>24 A. Yes.</p> <p>25 Q. And this critique of yours relates to</p>	<p style="text-align: right;">Page 213</p> <p>1 A. Correct.</p> <p>2 Q. And finally your subpart (e) of</p> <p>3 paragraph 30 relates to combining information and</p> <p>4 manual review as you say; right?</p> <p>5 A. That would be associated with the</p> <p>6 patients' economic loss class and the TPPs.</p> <p>7 Q. So paragraph 30(e) reflects the critique</p> <p>8 that relates to which classes?</p> <p>9 A. The TPP class and the consumer class,</p> <p>10 the economic damages.</p> <p>11 Q. Other than it sounds like the combining</p> <p>12 of information in paragraph 30(e), the only</p> <p>13 critiques you have of the economic loss -- strike</p> <p>14 that.</p> <p>15 The only critiques that you have here of</p> <p>16 the economic loss consumer class are those</p> <p>17 reflected in 30(e); right?</p> <p>18 MR. DORNER: Object to form.</p> <p>19 Characterization.</p> <p>20 You can answer.</p> <p>21 THE WITNESS: That's the only one</p> <p>22 reflected in the summary. If you give me a</p> <p>23 minute, I'll go through the detail to see if</p> <p>24 there's any others. There's more detail in my</p> <p>25 report, but I'm sure we'll get there.</p>

<p style="text-align: right;">Page 214</p> <p>1 BY MR. STANOCH:</p> <p>2 Q. Tell me what that is.</p> <p>3 A. It's covered in 88 and 89 paragraphs,</p> <p>4 but I would say that's a summary of those</p> <p>5 paragraphs.</p> <p>6 Q. Got it. So paragraphs 88, 89 again</p> <p>7 relate to the combining of data sources, as you</p> <p>8 say it, which was what paragraph 30(e) summarized;</p> <p>9 right?</p> <p>10 MR. DORNER: Object to the</p> <p>11 characterization.</p> <p>12 You can answer.</p> <p>13 THE WITNESS: Yes.</p> <p>14 BY MR. STANOCH:</p> <p>15 Q. And, look, I'm not trying to trick you,</p> <p>16 Mr. Kosty. I think, correct me if I'm wrong, at</p> <p>17 some point you talk about an exclusion of classes</p> <p>18 about defendants' employees. You recall that in</p> <p>19 your opinions; right?</p> <p>20 A. Yes.</p> <p>21 Q. I'm sorry. I didn't hear you.</p> <p>22 A. I'm sorry. Yes.</p> <p>23 Q. Thank you for that. And would that</p> <p>24 critique apply to all three of the proposed</p> <p>25 classes?</p>	<p style="text-align: right;">Page 216</p> <p>1 you opine on in this case as to the economic loss</p> <p>2 consumer case is combining data as elaborated in</p> <p>3 your report; correct?</p> <p>4 A. Yes.</p> <p>5 MR. DORNER: I'll object to the</p> <p>6 characterization. But keep going, Dave.</p> <p>7 BY MR. STANOCH:</p> <p>8 Q. And number two, the class exclusion</p> <p>9 relating to defendants' employees?</p> <p>10 MR. DORNER: Same objection.</p> <p>11 You can answer.</p> <p>12 THE WITNESS: Yes.</p> <p>13 BY MR. STANOCH:</p> <p>14 Q. Are there any other opinions that you're</p> <p>15 offering as to the economic loss consumer class</p> <p>16 besides those two we just listed?</p> <p>17 MR. DORNER: Same objection.</p> <p>18 You can answer.</p> <p>19 THE WITNESS: No.</p> <p>20 BY MR. STANOCH:</p> <p>21 Q. As to the medical monitoring class,</p> <p>22 again, one of your critiques relates to combining</p> <p>23 data as set forth in your report; right?</p> <p>24 A. Yes.</p> <p>25 Q. And the other is as summarized in</p>
<p style="text-align: right;">Page 215</p> <p>1 A. It would only apply to the consumer</p> <p>2 economic class for the patients specifically. Did</p> <p>3 I answer your question?</p> <p>4 Q. You did. Thanks. So I think after</p> <p>5 going through that, it sounds like there's two</p> <p>6 critiques then that you opine on in this case as</p> <p>7 to the economic loss consumer case. One is about</p> <p>8 combining data as elaborated in your report;</p> <p>9 correct?</p> <p>10 A. Yes.</p> <p>11 Q. And the second is the ability to exclude</p> <p>12 defendants' employees; correct?</p> <p>13 A. In this subsection (e) is what you're</p> <p>14 speaking to specifically; correct? Is there a way</p> <p>15 to turn this up? Can you hear me okay or not?</p> <p>16 Q. Now I can. So maybe if you make sure</p> <p>17 you lean into the mic. So it sounds like you said</p> <p>18 this subsection (e). Is that what you were</p> <p>19 talking about?</p> <p>20 A. Yes. That was my question. Were you</p> <p>21 referring just to this subsection (e)?</p> <p>22 Q. No, sir. I was running through your</p> <p>23 summary of opinions to help frame for our</p> <p>24 questions. And then the question I'll repose to</p> <p>25 you is: It sounds like your two critiques that</p>	<p style="text-align: right;">Page 217</p> <p>1 paragraph 30(b) about levels of exposure; right?</p> <p>2 A. For specific patients, yes.</p> <p>3 Q. And the same issue regarding exclusion</p> <p>4 of defendants' employees; right?</p> <p>5 MR. DORNER: Object to the form.</p> <p>6 But you can answer if you understand.</p> <p>7 THE WITNESS: What section are you</p> <p>8 referring to?</p> <p>9 BY MR. STANOCH:</p> <p>10 Q. I'm just asking you, sir. I'm trying to</p> <p>11 get all of your opinions critiquing the medical</p> <p>12 monitoring class. Then we can go through each of</p> <p>13 them.</p> <p>14 A. You were going through (a), (b). That's</p> <p>15 why I asked the question which one are you</p> <p>16 referring to. So can you repeat that question?</p> <p>17 Q. Sure. Your critique about excluding</p> <p>18 defendants' employees, would that apply to the</p> <p>19 medical monitoring class?</p> <p>20 A. Yes.</p> <p>21 Q. And then are there any other critiques</p> <p>22 of the medical monitoring class besides those</p> <p>23 three that we just listed that you're opining on</p> <p>24 in this case?</p> <p>25 A. Not that I recall.</p>

<p style="text-align: right;">Page 218</p> <p>1 Q. You make reference in paragraph 30 to 2 manual review. Do you see that, sir? 3 A. Yes. 4 Q. You see that; right? 5 A. I do. 6 Q. What do you mean by manual review as you 7 use the phrase in your report? 8 A. You would have to look at specific 9 documents or contact people for additional 10 information that would have to be somehow 11 documented to apply the various inclusions, 12 exclusions in this class. 13 Q. How do you use the phrase manual review 14 as it relates to data? 15 A. I don't believe I talked about that 16 context here, but manual review of data would be 17 the process of matching different data sources. 18 If you have disparate data sources, you have to 19 have a way to link them. 20 Oftentimes that's a manual review, at 21 least initially, so you can determine if you have 22 multiple sources how do they link to each other, 23 if at all, and if they do, then what's the 24 limitations to that linking, or are you happy with 25 the sufficiency of it.</p>	<p style="text-align: right;">Page 220</p> <p>1 particular task that may be necessary to identify 2 class members? 3 A. I do not. That was not part of my 4 assignment to try to cobble these data sources 5 together, no. 6 Q. And putting aside the cobbling together, 7 as you say, it is correct, is it not, that nowhere 8 do you purport to quantify how much manual review 9 would be required for any particular task that may 10 be necessary to identify class members? 11 A. No. I don't quantify the hours that 12 would be required to do these things, no. 13 Q. Do you propose in your report anywhere 14 any methodology for how you would attempt to 15 quantify the amount of manual review necessary to 16 perform any particular task to identify class 17 members? 18 A. That was not my assignment, no. 19 Q. You're familiar with the National 20 Council for Prescription Drug Programs; correct? 21 A. Yes. 22 Q. Can we call that NCPDP today? 23 A. Absolutely. 24 Q. And you understand, of course, that the 25 NCPDP have promulgated certain standards?</p>
<p style="text-align: right;">Page 219</p> <p>1 Q. Does the fact that some data 2 manipulation by a human being mean that it's 3 administratively infeasible to use that data to 4 identify class members? 5 MR. DORNER: Objection. To the extent 6 it calls for a legal conclusion. And 7 mischaracterization. 8 You can answer. 9 THE WITNESS: When you're linking 10 different datasets, you have to have some kind of 11 manual evaluation of those datasets unless it's 12 coming from the same system where you know the 13 database criteria and the keys to those database 14 tables. 15 BY MR. STANOCH: 16 Q. And the fact that you need a human being 17 to do what you just described, does that mean that 18 it's administratively infeasible to use that data 19 to identify class members? 20 MR. DORNER: Repeat objections. 21 You can answer. 22 THE WITNESS: No. 23 BY MR. STANOCH: 24 Q. Do you quantify anywhere in your report 25 how much manual review would be required for any</p>	<p style="text-align: right;">Page 221</p> <p>1 A. Yes. I'm a member of that organization. 2 Q. And what are the NCPDP data standards? 3 A. I don't know all of them in particular, 4 but the one that applies to this case is the D.0 5 telecommunications standard. 6 Q. And do those NCPDP standards relate to 7 the data fields used for communications for 8 adjudicating pharmacy claims? 9 A. Yes. That's the purpose of the 10 standard. 11 Q. Has that standard been in effect since 12 2003? 13 A. I'm trying to recall. I think it was a 14 little bit later than that. But it's the D.0 15 standard. The organization started with 16 Version 1. Once it became a HIPAA named standard, 17 then there was a whole process involved with 18 NCPDP, creating the new standard and, B, it had to 19 get approved through CMS and another committee or 20 two. 21 So it's been very difficult for the 22 industry to update that standard. So it's been in 23 use for a number of years. I'm not sure if it's 24 2003, but late 2000s, 2008 maybe is when it first 25 went into use.</p>

<p style="text-align: right;">Page 222</p> <p>1 Q. That's fair. Would you agree that since 2 approximately 2008, pharmacies have used those 3 NCPDP standards to process pharmaceutical claims? 4 A. Yes. 5 Q. Would you agree that since approximately 6 2008, PBMs have used the NCPDP standards to 7 process pharmaceutical claims? 8 A. Yes. 9 Q. Would you agree that to process 10 pharmaceutical claims, PBMs must be able to map 11 communications from pharmacies to their own claims 12 databases? 13 A. Yes. 14 Q. You don't identify any instance in your 15 report, do you, of where a PBM has not or cannot 16 map communications from pharmacies to their own 17 claims databases for pharmacy claims; right? 18 A. That's correct. 19 Q. Do the NCPDP standards contain a field 20 for NDC code for the drug dispensed by the 21 pharmacy? 22 A. Yes. 23 Q. You understand the NDC code allows 24 identification of the drug manufacturer? 25 A. I do.</p>	<p style="text-align: right;">Page 224</p> <p>1 Q. And do you agree that PBMs maintain 2 personal identifying information for the 3 prescriptions that are dispensed and communicated 4 to them by pharmacies? 5 A. Yes. 6 Q. Do you agree that pharmacies maintain 7 data on the amount paid by a consumer for a drug 8 dispensed? 9 MR. DORNER: Object to form. Vague. 10 You can answer. 11 THE WITNESS: Yes. 12 BY MR. STANOCH: 13 Q. Do you agree that PBMs maintain the 14 amount paid by a consumer for a drug dispensed by 15 a pharmacy that's communicating to that PBM? 16 A. Yes. 17 Q. Do you agree that pharmacies maintain 18 data on which pharmacy dispenses a drug to a 19 consumer? 20 A. Yes. 21 Q. Do you agree that PBMs maintain data on 22 which pharmacy dispenses a drug to a consumer from 23 the communications the PBM receives from the 24 pharmacies? 25 MR. DORNER: Objection to form. Vague.</p>
<p style="text-align: right;">Page 223</p> <p>1 MR. DORNER: I'll object to the 2 characterization. But you can keep going, Dave. 3 THE WITNESS: Let me add a 4 clarification. It identifies a supplier which may 5 be the manufacturer. Supplier, product code and 6 package size is the three components of the NDC. 7 BY MR. STANOCH: 8 Q. You agree that the NDC code identifies a 9 given drug's package size and type; right? 10 A. Yes. 11 Q. And you would agree the NDC number 12 identifies the product's strength, dosage form and 13 formulation? 14 A. Yes. 15 Q. Do you agree that pharmacies maintain 16 data about the drugs they dispense to consumers? 17 A. Yes. 18 Q. Would you agree that PBMs maintain data 19 on the pharmacy claims submitted to them by drugs 20 dispensed by pharmacies? 21 A. Yes. 22 Q. Do you agree that pharmacies maintain 23 personal identifying information for the consumers 24 to whom a prescription is dispensed? 25 A. Yes.</p>	<p style="text-align: right;">Page 225</p> <p>1 You can answer. 2 THE WITNESS: Yes. 3 BY MR. STANOCH: 4 Q. Do you agree that pharmacies maintain 5 the data on when a drug is dispensed to a 6 consumer? 7 A. Yes. 8 Q. Do you agree that PBMs maintain data on 9 when a drug is dispensed to a consumer from the 10 communications the PBM receives from the pharmacy? 11 A. Yes. 12 Q. Do you agree that pharmacies maintain 13 data on the state in which a drug is dispensed to 14 a consumer? 15 A. Yes. 16 Q. Do you agree that PBMs maintain data on 17 the state in which a drug is dispensed to a 18 consumer from the communications the PBM receives 19 from the pharmacy? 20 A. Yes. 21 Q. You do not specifically opine on how 22 long any specific pharmacy or PBM maintains 23 pharmacy claims data, do you? 24 A. Not in my report, no. 25 Q. In your report I believe at paragraph</p>

<p style="text-align: right;">Page 226</p> <p>1 159, you do allude to a Medicare requirement of 2 maintaining records for 10 years; correct? 3 A. Let me get there. But, yes, that's the 4 requirement for Med D programs. 5 Q. Are you familiar from your experience of 6 pharmacies maintaining pharmacy claims data for at 7 least 10 years? 8 MR. DORNER: Object to form. 9 You can answer. 10 THE WITNESS: It's up to the individual 11 pharmacy or pharmacy chain to decide how long they 12 want to keep it. Obviously, Med D is the longest 13 period of time. So like in this case, the 14 defendant retail pharmacies produced data I think 15 that went back to 2013 or so. 16 But anyway, it's up to the individual 17 pharmacy. They could delete data or archive it 18 earlier based on other provisions. But that's an 19 individual business decision of each of those 20 pharmacies. 21 BY MR. STANOCH: 22 Q. You're not offering any opinion in this 23 case, are you, that any specific pharmacy retained 24 pharmacy claims data for less than 10 years, are 25 you?</p>	<p style="text-align: right;">Page 228</p> <p>1 affirmatively deleted any pharmacy claims data; 2 right? 3 A. I have knowledge of that, no. 4 Q. And you have no knowledge about whether 5 any retail pharmacy defendant maintains pharmacy 6 claims data for less than 10 years, do you? 7 A. I don't know. 8 Q. And you didn't even look into that for 9 purposes of your report; correct? 10 A. That is correct. 11 Q. You allude to whether PBMs may store 12 data for certain periods of time in your paragraph 13 159; is that right? 14 A. Are you speaking of the second sentence 15 of that paragraph? 16 Q. Yes, sir. 17 A. Yes. I'm not aware of any legal 18 requirements for PBMs to store commercial claims 19 data for a specified period of time. 20 Q. You're not offering any opinion in this 21 case about how long any PBM retains pharmacy 22 claims data, do you? 23 A. I do not offer that opinion, no. 24 Q. And you don't know sitting here one way 25 or the other, do you, about how long any</p>
<p style="text-align: right;">Page 227</p> <p>1 MR. DORNER: Object to form. Vague. 2 You can answer. 3 THE WITNESS: That's not covered in my 4 report. I don't know what individual pharmacy 5 chains do in that regard. 6 BY MR. STANOCH: 7 Q. You're not offering any opinion in this 8 case about any specific pharmacy deleting any 9 pharmacy claims data, are you? 10 A. I'm not. 11 Q. As part of your opinions in this case, 12 did you review any document retention policies for 13 the retail pharmacy defendants? 14 A. No, I did not. 15 Q. Would you be surprised to know that the 16 produced policies set a record retention for 10 17 years on pharmacy claims? 18 MR. DORNER: Object to the 19 characterization. Lacks foundation. 20 You can answer if you know. 21 THE WITNESS: I would not be surprised 22 due to the Medicare Part D requirements, no. 23 BY MR. STANOCH: 24 Q. You're certainly not offering any 25 opinion that any retail pharmacy defendant</p>	<p style="text-align: right;">Page 229</p> <p>1 particular PBM maintains any pharmacy claims data, 2 do you? 3 A. I don't. 4 Q. And did you look into the document 5 retention policies for any PBM in connection with 6 your opinions in this case? 7 A. I did not. 8 Q. You're not offering any opinion in this 9 case that any PBM affirmatively deleted pharmacy 10 claims data, are you? 11 A. I'm not. 12 Q. Stand by for an exhibit, sir. Are you 13 familiar with entity known as Express Scripts? 14 A. Yes. 15 Q. They're a PBM; correct? 16 MR. DORNER: Object to form. 17 You can answer. 18 THE WITNESS: Yes. I'm trying to -- is 19 the exhibit going to come up here? 20 BY MR. STANOCH: 21 Q. I haven't pulled up an exhibit, sir. 22 A. I thought you were going to reference 23 one. 24 Q. Stand by for the exhibit, but before we 25 get there, you're familiar with Express Scripts;</p>

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[REDACTED]

Page 236

[REDACTED]

9 BY MR. STANOCH:

10 Q. Are you familiar with the entity known

11 as Navitus?

12 A. Yes.

13 Q. What is Navitus?

14 A. Navitus is a regional PBM.

15 Q. Have you ever done any work with them

16 outside of litigation?

17 A. Yes; many, many years ago.

18 Q. What do you remember doing with Navitus?

19 MR. DORNER: And I'll just caution to

20 the extent any of this is covered by

21 confidentiality designation.

22 THE WITNESS: This one is a long time.

23 We worked with their pharmacy director on various

24 activities to help them run a better pharmacy

25 program in the PBM.

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[REDACTED]

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1 BY MR. STANOCH:

2 Q. Navitus is a PBM you said; right?

3 A. Yes.

4 Q. I'm going to mark the next exhibit,

5 Exhibit 9. Stand by.

6 (Kosty Exhibit 9 was marked.)

7 BY MR. STANOCH:

8 Q. Let me know when you can access that

9 document.

10 A. It came up in small format. I was able

11 to figure out how to increase it. Okay. Got it.

12 Q. You see this appears to be a Navitus

13 Record Retention and Record Availability Schedule?

14 A. Yes.

15 Q. Do you see here there's a few paragraphs

16 under Requirements?

17 A. Yes. It leads me to believe -- yeah,

18 the first sentence leads me to believe this

19 applies to the Medicare policy.

20 Q. The sentence reads, "PBMs as first tier

21 and downstream entities must comply with Medicare

22 laws, regulations and CMS instructions," paren,

23 citation, "and agree to audits and inspection by

24 CMS and/or its designees and to cooperate, assist

25 and provide information as requested and maintain

<p style="text-align: right;">Page 238</p> <p>1 records a minimum of 10 years."</p> <p>2 Did I read that right?</p> <p>3 A. Yes.</p> <p>4 Q. Do you have any reason to disagree with</p> <p>5 that statement from Navitus?</p> <p>6 A. Not as it applies to Medicare, no.</p> <p>7 Q. You don't offer any opinion in your</p> <p>8 report whatsoever about whether any pharmacy or</p> <p>9 PBM retains non-Medicare records for less than 10</p> <p>10 years; right?</p> <p>11 MR. DORNER: Object to form.</p> <p>12 You can answer.</p> <p>13 THE WITNESS: I do not.</p> <p>14 BY MR. STANOCH:</p> <p>15 Q. You can put that aside. Back to the</p> <p>16 NCPDP standards, Mr. Kosty, do those standards</p> <p>17 have a field for group number?</p> <p>18 A. Yes.</p> <p>19 Q. Do those standards have a field for</p> <p>20 cardholder ID?</p> <p>21 A. Yes.</p> <p>22 Q. Do those standards have a code for, I</p> <p>23 guess, a person, a person code?</p> <p>24 A. Person code, yes.</p> <p>25 Q. Do those standards have a code for birth</p>	<p style="text-align: right;">Page 240</p> <p>1 Q. And cardholder ID field, sir, what does</p> <p>2 that show?</p> <p>3 A. It's whatever the card issuer designates</p> <p>4 as the cardholder ID.</p> <p>5 Q. That would be the ID that was assigned</p> <p>6 to the particular person who has the card?</p> <p>7 A. Right. Whoever issued the card would</p> <p>8 assign that number, yes.</p> <p>9 Q. And person code, what does that reflect?</p> <p>10 A. Well, person code reflects probably at a</p> <p>11 higher level the relationship of that patient to</p> <p>12 the cardholder. So some systems require a person</p> <p>13 code. Others might have a different ID for each</p> <p>14 member of your family, for example.</p> <p>15 So the person code is typically used</p> <p>16 when there's one ID for the family, and then it</p> <p>17 identifies the individual patient within that</p> <p>18 family who that prescription is being filled for.</p> <p>19 Q. Understood. So hypothetically I could</p> <p>20 have a card where my person code is 1 and my</p> <p>21 spouse's code would be 2?</p> <p>22 A. Correct.</p> <p>23 Q. And that's the purpose of the person</p> <p>24 code field, to differentiate between persons under</p> <p>25 the same plan; right?</p>
<p style="text-align: right;">Page 239</p> <p>1 date?</p> <p>2 A. They have a field for birth date, yes.</p> <p>3 Q. Do those standards have a field for</p> <p>4 name?</p> <p>5 A. Yes.</p> <p>6 Q. Do those standards have a field for</p> <p>7 address?</p> <p>8 A. The patient's address, yes.</p> <p>9 Q. Correct. When we're referring to birth</p> <p>10 date, we're referring to the patient's birth date;</p> <p>11 correct?</p> <p>12 A. Yes.</p> <p>13 Q. And when we're referring to name, that</p> <p>14 would be the patient's name; correct?</p> <p>15 A. Correct.</p> <p>16 Q. And as you said, the address field would</p> <p>17 be the patient's address; correct?</p> <p>18 A. Yes.</p> <p>19 Q. And the group number field would be</p> <p>20 what?</p> <p>21 A. It would be an identifier that tells the</p> <p>22 PBM system as one component how to process the</p> <p>23 claim. So a group number can be anything,</p> <p>24 anything. It's up to the card issuer to determine</p> <p>25 what the group number is.</p>	<p style="text-align: right;">Page 241</p> <p>1 A. No. It would be under the same</p> <p>2 cardholder.</p> <p>3 Q. Correct.</p> <p>4 A. So it may be an employee. So the</p> <p>5 employee has coverage, and if he has family</p> <p>6 coverage or if she has family coverage, then those</p> <p>7 dependents would be listed. In some cases the</p> <p>8 person code is used to identify those people.</p> <p>9 Q. Do you agree that within a single system</p> <p>10 you can follow a particular consumer over time</p> <p>11 using the group number, cardholder ID, person</p> <p>12 code, birth date, name and address fields?</p> <p>13 MR. DORNER: Object to form.</p> <p>14 You can answer.</p> <p>15 THE WITNESS: Maybe. If that person</p> <p>16 stays within the same group for that time period,</p> <p>17 yes, you could track that person. Let's say you</p> <p>18 had a person that moved to a different group.</p> <p>19 Then you wouldn't be able to track them with that</p> <p>20 group number key.</p> <p>21 BY MR. STANOCH:</p> <p>22 Q. Because the group number might change?</p> <p>23 A. Exactly.</p> <p>24 Q. But you would not expect, for</p> <p>25 instance -- strike that.</p>

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<p>1 Do you agree that you can map equivalent 2 data fields from different software packages using 3 the field names used? 4 MR. DORNER: Object to form. 5 You can answer. 6 THE WITNESS: Can you be more specific? 7 The field names used, what specific fields are you 8 talking about? 9 BY MR. STANOCH: 10 Q. Well, let's keep it confined to the six 11 we just identified, group number, cardholder ID, 12 person code, birth date, name and address. 13 A. Can you repeat your question now? 14 Q. Sure. Do you agree that you can map 15 equivalent data fields from different software 16 packages using the six fields we just described? 17 A. For the most part, yes. The only caveat 18 I would have, if it's the same -- well, you would 19 need to know who the PBM was that retained that 20 data because if you had a person, maybe they 21 changed PBMs or their health plan changed PBMs or 22 their employer changed benefits and went to a 23 different PBM. You would not be able to track 24 that across the different PBM systems. 25 But within one PBM system that was</p>	<p>1 ensure that you were looking at the same patient 2 record. 3 BY MR. STANOCH: 4 Q. You agree that PBMs and pharmacies can 5 only transmit data between themselves if the data 6 is understandable by each entity; right? 7 A. Yes. 8 Q. And you agree that PBMs and pharmacies 9 can only transmit data between themselves if the 10 data are stored in each entity's respective 11 system; right? 12 A. Yes. It's got to be stored somewhere to 13 transmit it. 14 Q. Right. When a data transmission from a 15 pharmacy at a point of dispensement goes to a PBM, 16 that data doesn't disappear. Each entity would 17 have a record of the transaction; right? 18 A. That's correct. 19 Q. In fact, if there's any data missing 20 during that communication between the pharmacy and 21 the PBM, can the transaction be completed? 22 A. It depends. We've talked, I think, six 23 key fields here. It depends on the PBM claims 24 processing system, what fields they're requiring 25 to approve a claim and process it. So if they</p>
Page 243	Page 245
<p>1 responsible for that claim you could track it. 2 Q. You could map data from equivalent 3 fields across systems in certain circumstances; 4 correct? 5 MR. DORNER: Object to form. 6 You can answer. 7 THE WITNESS: Yes. In certain 8 circumstances, yes. 9 BY MR. STANOCH: 10 Q. For instance, let's take a field for 11 birth date. Okay? 12 A. Um-hum. 13 Q. If I go to pharmacy one and they have my 14 birth date, then I go to pharmacy two and they 15 have my birth date, those fields, everything else 16 aside, could be mapped; correct? 17 A. That would be one key to the mapping, 18 yes. 19 Q. And the process you would use for the 20 mapping would be similar for other available 21 fields; correct? 22 MR. DORNER: Objection. Form. 23 You can answer. 24 THE WITNESS: Yes. You would try to get 25 as many key fields as possible to be able to</p>	<p>1 only use four of those fields and the other two 2 are blank, it doesn't matter. 3 But if they require all six fields, they 4 would have to have information that could be 5 validated on the PBM side. 6 Q. You're familiar with the term data 7 dictionaries; right? 8 A. Yes. 9 Q. What does that mean to you? 10 A. It's a description of the data 11 attributes of the fields within a system. 12 Q. In laymen's parlance, it's sort of a 13 key, if you will, for what fields or values mean 14 in pharmacy claims data? 15 MR. DORNER: Object to the 16 characterization. 17 You can answer. 18 THE WITNESS: Yes. But organizations 19 may keep other data that's not part of the 20 standard, and that would be included also in their 21 data dictionary, assuming they have good IT 22 hygiene practices. 23 BY MR. STANOCH: 24 Q. In your experience, do PBMs and 25 pharmacies maintain data dictionaries for the</p>

<p>Page 246</p> <p>1 fields and values in their pharmacy claims data?</p> <p>2 A. Somewhere in their IT department, they</p> <p>3 might have a data dictionary. My experiences</p> <p>4 running a PBM is I didn't go to a data dictionary</p> <p>5 every day to look at fields. I knew what they</p> <p>6 meant. So, likely somewhere in the organization</p> <p>7 you could find one.</p> <p>8 Q. For purposes of your opinions in this</p> <p>9 case, you did not undertake to collect any data</p> <p>10 dictionaries from any PBM, pharmacy or other</p> <p>11 entity, did you?</p> <p>12 A. I did not.</p> <p>13 Q. You talk a little bit about potential</p> <p>14 difficulties in merging or matching data across</p> <p>15 different entities, pharmacy claims databases; is</p> <p>16 that right?</p> <p>17 A. Yes.</p> <p>18 Q. For that part of that discussion, you</p> <p>19 cite the Pew Charitable Trust study from 2018;</p> <p>20 right?</p> <p>21 A. Yes.</p> <p>22 Q. And the Pew Charitable Trust study, that</p> <p>23 was not confined to matching just pharmacy or PBM</p> <p>24 data; correct?</p> <p>25 MR. DORNER: Object to form.</p> <p>Page 247</p> <p>1 You can answer.</p> <p>2 THE WITNESS: If I recall correctly, the</p> <p>3 Pew study was looking at records within a health</p> <p>4 plan using their patient management system. So,</p> <p>5 yeah, they indicated there was, I think,</p> <p>6 18 percent duplication of patient records within</p> <p>7 their medical management system and that health</p> <p>8 plan.</p> <p>9 BY MR. STANOCH:</p> <p>10 Q. Right. The Pew Charitable Trust study</p> <p>11 was talking about matching patient medical records</p> <p>12 such as doctor's notes, lab diagnostics and the</p> <p>13 things of that nature; right?</p> <p>14 A. Yes. The same thing happens in pharmacy</p> <p>15 systems where you have to go from -- you could</p> <p>16 create duplicate records within your pharmacy</p> <p>17 system. If you went to a different pharmacy, if</p> <p>18 you were a snow bird and had two addresses, then</p> <p>19 you could potentially create additional records</p> <p>20 for the same patient.</p> <p>21 That's always been a challenge for</p> <p>22 pharmacies because you obviously would want the</p> <p>23 same patient in one record.</p> <p>24 Q. The Pew Charitable Trust was talking</p> <p>25 about medical records. They were not talking</p>	<p>Page 248</p> <p>1 specifically about matching PBM and pharmacy</p> <p>2 claims data; correct?</p> <p>3 A. Yes. That was not the nature of the</p> <p>4 study.</p> <p>5 Q. In fact, I can put it in front of you if</p> <p>6 you like. The Pew charitable Trust study you cite</p> <p>7 does not even mention PBMs, does it?</p> <p>8 A. No.</p> <p>9 Q. And you agree that pharmaceutical claims</p> <p>10 adjudication depends on different data than the</p> <p>11 data being used for the medical claims</p> <p>12 adjudication; right?</p> <p>13 A. Yes. It's specific to pharmacy.</p> <p>14 Q. In looking at your report in paragraph</p> <p>15 158, sir --</p> <p>16 A. Yes.</p> <p>17 Q. -- other than your footnote 298 to the</p> <p>18 Pew Charitable Trust study we're talking about,</p> <p>19 you don't cite any other information or source</p> <p>20 regarding the difficulties with matching records;</p> <p>21 correct?</p> <p>22 MR. DORNER: Object to form.</p> <p>23 You can answer.</p> <p>24 THE WITNESS: I don't cite another</p> <p>25 source, but my experience in the industry has</p> <p>Page 249</p> <p>1 indicated the challenges there are matching across</p> <p>2 these different systems when, for example, a TPP</p> <p>3 may change benefits and use one PBM for a two-year</p> <p>4 period and maybe switch to another PBM. There's</p> <p>5 movement between PBMs. There's movement of</p> <p>6 patients between employers. Perhaps someone got a</p> <p>7 new job.</p> <p>8 The other component that is tricky is</p> <p>9 people get married. They get divorced. They have</p> <p>10 name changes for whatever reason. So all those</p> <p>11 issues make it difficult to track across different</p> <p>12 systems for patient information.</p> <p>13 BY MR. STANOCH:</p> <p>14 Q. You mentioned TPP may switch PBMs. Is</p> <p>15 that what you said?</p> <p>16 A. Yes.</p> <p>17 Q. For instance, a TPP may be using one PBM</p> <p>18 and then it may use a different PBM. Is that what</p> <p>19 you're saying?</p> <p>20 A. Yes. It's an ongoing competition in the</p> <p>21 marketplace to determine what PBM to use and what</p> <p>22 benefits that are offered that are attractive to</p> <p>23 employers.</p> <p>24 Q. And the risk you're opining on in that</p> <p>25 instance is that the TPP may show up twice, once</p>
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1 in the first PBM's data and then again in the
 2 second PBM's data; right?
 3 A. Yes. They may be in multiple systems.
 4 They may have new cards issued to their
 5 membership. There's a number of different
 6 components that introduce variability into these
 7 systems.
 8 Q. So that risk there as it comes to
 9 identifying TPPs is that there's twice as many
 10 opportunities to identify that TPP; right?
 11 MR. DORNER: Object to form.
 12 Mischaracterization.
 13 You can answer.
 14 THE WITNESS: Yeah, if it's in the
 15 multiple systems, then you would have many
 16 opportunities, yes.
 17 BY MR. STANOCH:
 18 Q. You mentioned this, I think, a moment
 19 ago. In your experience, have you, in fact,
 20 worked on merging claims data from the two
 21 different entities using NCPDP fields?
 22 A. Yes.
 23 Q. Have you done that for PBMs?
 24 A. Yes.
 25 Q. You were able to merge claims data from

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1 the two different PBMs for work that you or your
 2 consulting firm was doing?
 3 A. Yeah. We had two projects where we
 4 helped a PBM convert claims processing systems
 5 from one PBM to the other. I think I mentioned in
 6 the report somewhere there's a lot of individual
 7 business decisions that need to be made when you
 8 do claims conversion.
 9 You have to decide how much prescription
 10 data to convert. How are you going to use that
 11 data? You're going to have make sure that you can
 12 map the data into the new system or the successor
 13 claims processing system. Then you got to test
 14 that information to make sure the mapping is
 15 correct, and then you have as much data as
 16 management decided to ingest into the new systems.
 17 That's one of the management decisions,
 18 is how much data do you need and why and why do we
 19 load any more data than is absolutely required.
 20 Typically, it's more of a clinical discussion on
 21 how far back in the patient profile do you want to
 22 look for those clinical edits.
 23 Q. What fields did you use to map the
 24 claims data between the two PBMs that you were
 25 analyzing?

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1 A. The six fields that you identified are
 2 key fields. Other fields would be the pharmacy.
 3 Those would probably be the majority of them,
 4 unless there were other components, prior
 5 authorizations or clinical edits.
 6 One of the things that when you have to
 7 do these projects, you look at minimizing patient
 8 disruption. So if you're able to convert
 9 information that precludes calling your help desk
 10 or the patient going back to their benefits
 11 office, you try to look at those situations. But
 12 six I think at a minimum you would need, plus the
 13 pharmacy ID.
 14 Q. That would be a pharmacy ID for the
 15 particular pharmacy dispensing a particular drug?
 16 A. Correct.
 17 Q. How about the field for NDC code?
 18 A. Yes.
 19 Q. How about the field for date of service?
 20 A. Yes. That's part of the conversion
 21 process. You look at how long back you have to
 22 use the date of service to make that decision.
 23 Q. Date of service is the date a pharmacy
 24 dispensed a drug to a consumer; right?
 25 A. It's the date they filled the

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1 prescription. Whether it was dispensed to the
 2 consumer, we don't know, but they sent it through
 3 the claims adjudication process on that date.
 4 Q. Fair enough. Was your
 5 engagement -- strike that.
 6 Which PBMs data were you working on when
 7 you were doing this claims data merger analysis?
 8 A. Catalyst Rx and Systems Excellence at
 9 the time. Those two companies eventually merged
 10 into Catamaran Rx.
 11 Q. You said the letters X -- I'm sorry.
 12 The second one you said, that's also known as SXC;
 13 right?
 14 A. Yeah. The name of the company changed
 15 over the years.
 16 Q. Got it. And you said ultimately
 17 Catalyst Rx and SXC successfully merged into the
 18 PBM known as Catamaran?
 19 A. Correct.
 20 Q. And your work in analyzing the Catalyst
 21 and SXC's PBM claims data was part of the
 22 underlying work that led to that successful
 23 merger; right?
 24 A. Yes. We actually converted Catalyst Rx
 25 from an Argus claims processing system to the SXC

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1 system.

2 Q. You just faded out. I heard you

3 converted the Catalyst from an Argus claims

4 processing system to a what?

5 A. SXC.

6 Q. So you essentially -- you can use your

7 own words if I'm wrong -- you essentially were

8 able to convert the Catalyst PBM pharmacy claims

9 data to the SXC pharmacy claims data platform?

10 A. Yes.

11 Q. If you can go to paragraph 152 of your

12 report, sir. Let me know when you're there.

13 A. Okay.

14 Q. Here you talk in part about Ms. Craft's

15 report, about the data from the large PBMs and

16 retail pharmacy data in this case could be

17 expected to cover up to 98 percent of class

18 purchases. Do you see that?

19 A. Yes.

20 Q. You don't offer any specific opinion

21 regarding that characterization of that

22 combination to be expected to cover up to

23 98 percent of class purchases of valsartan, do

24 you?

25 A. No. I note that the time and expense

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1 required to obtain data from all these entities is

2 the issue at hand here.

3 Q. You don't quantify either here in

4 paragraph 152 or anywhere else how much time and

5 expense would be required to do that combination;

6 correct?

7 A. That was not part of my assignment, no.

8 Q. In the next paragraph, again you do not

9 specifically refute Ms. Craft's statement that the

10 top six PBMs processed between 89 to 96 percent of

11 U.S. prescription volume annually between 2015 and

12 2018; correct?

13 A. Correct.

14 MR. DORNER: Object to form.

15 You can keep going.

16 BY MR. STANOCH:

17 Q. Do you agree with Ms. Craft's statement,

18 that the top six PBMs processed between 89 and 96

19 percent of U.S. prescription volume annually

20 between 2015 and 2018?

21 A. Based on the source she provides, yes.

22 There's been consolidation. But as I also note,

23 there's an additional 60 PBMs in the United States

24 that do similar functions.

25 Q. You go on to talk about that in this

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1 paragraph 153; right?

2 A. Yes.

3 Q. You say, "PBM consolidation over time

4 may make data production review more difficult as

5 information needs to be pulled and combined from

6 multiple claims processing systems, which have

7 different field naming conventions and meaning."

8 Correct?

9 A. Yes.

10 Q. You don't identify which, if any, PBMs

11 have combined over time that may make data

12 production and review more difficult, correct, in

13 this paragraph?

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 It's one of those things you have to as

20 a business perspective decide what's the value for

21 me to exert the energy to convert clients to a

22 different claims processing system, or do I wait a

23 period of time until their renewal is up and they

24 renew with the company and then convert them to

25 the new system.

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1 So there's management decisions made.

2 So you may run systems in parallel. You might

3 have systems that have different versions. So

4 there's a number of components that go into making

5 that management decision on what claims processing

6 system to use or if you use both of them or

7 multiple systems.

8 [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 Q. You don't identify any other potential

16 examples, do you?

17 A. I did not in this report. There's many

18 examples of PBM acquisition.

19 Q. Well, you understand I'm here to depose

20 you about the confines of your opinions as set

21 forth in your report; right?

22 A. Yes.

23 Q. Your report contains all the opinions

24 you intend to offer at this point in this case?

25 A. Yes.

<p>Page 258</p> <p>1 [REDACTED] 2 [REDACTED] 3 [REDACTED] 4 [REDACTED] 5 [REDACTED] 6 [REDACTED] 7 [REDACTED] 8 [REDACTED] 9 [REDACTED] 10 [REDACTED] 11 [REDACTED] 12 [REDACTED] 13 [REDACTED] 14 [REDACTED] 15 [REDACTED] 16 [REDACTED] 17 [REDACTED] 18 [REDACTED] 19 [REDACTED] 20 [REDACTED] 21 [REDACTED] 22 [REDACTED] 23 [REDACTED] 24 [REDACTED] 25 [REDACTED]</p>	<p>Page 260</p> <p>1 opinion as to subpoenaing claims data from PBMs, 2 are you? 3 MR. DORNER: Object to the form. 4 You can answer if you understand. 5 THE WITNESS: I don't believe so, no. 6 BY MR. STANOCH: 7 Q. You've never been involved in a 8 litigation subpoena to a PBM for pharmacy claims 9 data; is that correct? 10 A. That's not correct, no. 11 Q. You have been involved in that? 12 A. Yes. I have been involved in that, yes. 13 Q. Do you offer any opinions in this case 14 concerning the process for subpoenaing pharmacy 15 claims data from PBMs? 16 A. No, I have not. There's nothing in my 17 report that addresses that issue. 18 Q. So you're not opining, for instance, and 19 I'll remind you you're under oath, sir, on how 20 long the subpoena process may take to obtain 21 pharmacy claims data from a PBM? 22 MR. DORNER: Object to form. Outside 23 the scope. Argumentative. 24 You can answer. 25 THE WITNESS: I'm looking to see where</p>
<p>Page 259</p> <p>1 [REDACTED] 2 [REDACTED] 3 [REDACTED] 4 [REDACTED] 5 [REDACTED] 6 [REDACTED] 7 [REDACTED] 8 [REDACTED] 9 [REDACTED] 10 [REDACTED] 11 [REDACTED] 12 [REDACTED] 13 [REDACTED] 14 [REDACTED] 15 MR. DORNER: Hey, Dave, we're a little 16 over an hour. I don't know where a good place to 17 break is, but when you get there, let's go ahead 18 and take a short one. 19 MR. STANOCH: Sure. We'll go a few more 20 minutes just to round this out, Mr. Dorner, if 21 that's okay with your witness, and then we can 22 take a break, absolutely. 23 MR. DORNER: Sure. 24 BY MR. STANOCH: 25 Q. Mr. Kosty, you're not offering any</p>	<p>Page 261</p> <p>1 they characterize it, but I believe I use the term 2 burdensome. I'm trying to figure out which 3 paragraph that's at. Let me look. 4 BY MR. STANOCH: 5 Q. Well, sir, you said you're not offering 6 any opinion on subpoenaing pharmacy claims data 7 from PBMs; correct? 8 A. Yes. 9 Q. And I'm happy to share my screen, but I 10 can't even find the word subpoena in your report. 11 Would that surprise you? 12 A. No. 13 Q. So again, you're not opining, sir, on 14 how long the subpoena process may take to obtain 15 pharmacy claims data from a PBM, are you? 16 MR. DORNER: Object to form. 17 Characterization. 18 You can answer. 19 THE WITNESS: No. 20 BY MR. STANOCH: 21 Q. You're aware that -- I think we 22 established this -- some of the retail pharmacy 23 defendants in this case have corporate affiliates 24 that are PBMs; right? 25 A. Yes.</p>

<p style="text-align: right;">Page 262</p> <p>1 Q. ESI is one of them; right?</p> <p>2 A. Yes.</p> <p>3 Q. CVS Caremark; right?</p> <p>4 A. Yes.</p> <p>5 Q. OptumRx; right?</p> <p>6 A. Yeah. Their mail service is part of the</p> <p>7 PBM, yes.</p> <p>8 Q. And while they may not be a defendant,</p> <p>9 Humana Pharmacy also has a PBM, a Humana</p> <p>10 affiliate; right?</p> <p>11 A. Yes.</p> <p>12 Q. Did you talk to anyone at any of those</p> <p>13 retail pharmacy defendants about what it would</p> <p>14 take to obtain PBM pharmacy claims data from their</p> <p>15 PBM affiliates?</p> <p>16 MR. DORNER: Object to form.</p> <p>17 MS. KAPKE: Object to form.</p> <p>18 MR. DORNER: Vague.</p> <p>19 You can answer.</p> <p>20 THE WITNESS: No, I did not speak</p> <p>21 directly to any retailers or pharmacy defendants.</p> <p>22 BY MR. STANOCH:</p> <p>23 Q. I'm sorry. Are you done?</p> <p>24 A. Or pharmacy defendants.</p> <p>25 Q. Did you communicate with any retail</p>	<p style="text-align: right;">Page 264</p> <p>1 regarding the process that would be involved to</p> <p>2 obtain PBM claims data from the retail pharmacy</p> <p>3 defendants' PBM affiliates in this case?</p> <p>4 MR. DORNER: Object to form. Vague.</p> <p>5 You can answer.</p> <p>6 THE WITNESS: No.</p> <p>7 MS. KAPKE: I'll join that objection.</p> <p>8 And since you asked the basis of my objection, I</p> <p>9 think his report speaks for itself on what he was</p> <p>10 provided. And with that objection, I'll let him</p> <p>11 go ahead and answer.</p> <p>12 THE WITNESS: No.</p> <p>13 BY MR. STANOCH:</p> <p>14 Q. You opine in paragraph 160 of your</p> <p>15 report, sir -- tell me when you're there. Are you</p> <p>16 on paragraph 160, sir?</p> <p>17 A. Yes.</p> <p>18 Q. Very good. I just want to make sure</p> <p>19 we're on the same page. Here you reference an</p> <p>20 OptumRx declaration; correct?</p> <p>21 A. Yes.</p> <p>22 Q. And you reference claims data that may</p> <p>23 be archived were not as readily accessible as more</p> <p>24 recent claims. Do you see that?</p> <p>25 A. Yes.</p>
<p style="text-align: right;">Page 263</p> <p>1 pharmacy defendant for purposes of preparing your</p> <p>2 opinions in this case?</p> <p>3 MS. KAPKE: Object to form.</p> <p>4 A. No.</p> <p>5 MR. STANOCH: What's the form objection,</p> <p>6 Ms. Kapke?</p> <p>7 MS. KAPKE: You're asking him if he's</p> <p>8 communicated with the defendants, and I frankly</p> <p>9 don't know what you mean by that, if you mean</p> <p>10 counsel or if you mean directly with the</p> <p>11 defendants. If you're talking counsel, he has</p> <p>12 been retained by counsel for the retail pharmacy</p> <p>13 defendants, and those communications are</p> <p>14 privileged.</p> <p>15 I don't understand your question. So</p> <p>16 I'm not going to instruct him further. But if you</p> <p>17 want to clarify what you're talking about, then I</p> <p>18 will make further objections.</p> <p>19 BY MR. STANOCH:</p> <p>20 Q. Mr. Kosty, did you communicate with any</p> <p>21 business personnel at any retail pharmacy</p> <p>22 defendant for purposes of preparing your opinions</p> <p>23 in this case?</p> <p>24 A. No.</p> <p>25 Q. Were you provided any information</p>	<p style="text-align: right;">Page 265</p> <p>1 Q. You never analyzed how long it would</p> <p>2 take any PBM to produce archived claims data, did</p> <p>3 you?</p> <p>4 A. That was not part of my assignment, no.</p> <p>5 Q. You never analyzed how long it would</p> <p>6 take any PBM to produce pharmacy claims data that</p> <p>7 is not as readily accessible, did you?</p> <p>8 A. No. That was not part of my assignment.</p> <p>9 Q. Do you have any understanding about what</p> <p>10 archived data means?</p> <p>11 A. Yes.</p> <p>12 Q. Do you offer any opinions in your report</p> <p>13 as to archived data?</p> <p>14 A. No.</p> <p>15 Q. So you're not opining in this case then</p> <p>16 how long it would take any PBM to produce archived</p> <p>17 pharmacy claims data; correct?</p> <p>18 A. Correct.</p> <p>19 Q. And you're not opining in this case how</p> <p>20 long it would take any PBM to produce pharmacy</p> <p>21 claims data that is not as readily accessible;</p> <p>22 correct?</p> <p>23 A. That is correct.</p> <p>24 Q. Have you ever worked in any litigation</p> <p>25 context to obtain archived data?</p>

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1 A. Could you explain what you mean by
2 litigation context?
3 Q. Have you ever been retained in any case
4 in which your work included obtaining archived
5 data?
6 A. No.
7 Q. Have you ever been retained in any case
8 in which your work included obtaining not readily
9 accessible data?
10 A. No.
11 Q. Now might be a good time to honor your
12 counsel's request for a break, sir.
13 A. Yes. Let's do that. You said 10
14 minutes?
15 MR. STANOCH: Off the record.
16 THE VIDEOGRAPHER: Off the record 4:04.
17 (Recess from 4:04 p.m. to 4:19 p.m.)
18 THE VIDEOGRAPHER: We are back on the
19 record at 4:19.
20 BY MR. STANOCH:
21 Q. Welcome back, Mr. Kosty. Just yes/no.
22 Did you talk to your counsel during the break?
23 A. Yes.
24 Q. Did you talk to anyone else besides your
25 counsel during the break?

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1 A. No.
2 Q. Did you communicate via email, text or
3 telephone with anybody during the break?
4 A. No.
5 Q. Did you look at any documents during the
6 break?
7 A. No.
8 Q. You did not conduct any literature
9 review for purposes of quantifying the feasibility
10 of combining claims data from different sources,
11 did you?
12 MR. DORNER: Object to form.
13 You can answer.
14 THE WITNESS: No.
15 BY MR. STANOCH:
16 Q. So you don't know what published
17 literature may exist concerning the feasibility of
18 combining claims data; you don't have any opinions
19 on that in this case?
20 A. I did not research that in the
21 literature, no.
22 Q. Stand by. I'm marking Exhibit 10, sir.
23 It should be in your folder. I'll share my screen
24 as well.
25 (Kosty Exhibit 10 was marked.)

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1 BY MR. STANOCH:
2 Q. Can you see it?
3 A. I'm bringing it up.
4 Q. Tell me when you're there.
5 A. All right. It's up.
6 Q. This appears to be an article
7 entitled "The Epidemiology of Prescriptions
8 Abandoned at the Pharmacy" from the Annals of
9 Internal Medicine; is that right?
10 A. That is the title of the article, yes.
11 Q. Have you seen this before?
12 A. I have not.
13 Q. If you would scroll down to the second
14 page, sir. Are you there?
15 A. I'm getting there. Just trying to get
16 an understanding what this article is about.
17 Okay.
18 Q. And you see here as part of what the
19 authors of this article did is they said, "...we
20 merged the database from a large retail pharmacy
21 chain with a database from a large pharmacy
22 benefits manager (PBM)."
23 Do you see that?
24 MR. DORNER: I'll object to form just to
25 the extent this is a document several pages in

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1 length that Mr. Kosty has never seen. So I'll
2 object to the form in that sense.
3 But other than that, you can continue.
4 THE WITNESS: Yeah, so the title is
5 Epidemiology of Prescriptions Abandoned at the
6 Pharmacy. Okay. So that's the intent. What
7 section did you highlight?
8 BY MR. STANOCH:
9 Q. I'll repeat it. Do you see on page 2
10 the authors of this study say, "...we merged the
11 database from a large retail pharmacy chain with a
12 database from a large pharmacy benefits manager
13 (PBM)"?
14 A. Yes. That's what it says.
15 Q. And you see in the right-hand column
16 they state, "Electronic pharmacy data from the
17 retail pharmacy and PBM were matched on pharmacy
18 store number, prescription number, fill date and
19 patient zip code. We successfully matched
20 99.93 percent of retail transactions with pharmacy
21 data."
22 Do you see that?
23 A. You've read that correctly.
24 MR. DORNER: Same objection as my
25 previous.

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1 BY MR. STANOCH:
2 Q. Do you have any basis to disagree with
3 the authors' statements regarding their
4 99.93 percent match of the pharmacy and PBM
5 pharmacy data that they were working with?
6 MR. DORNER: Same objection with respect
7 to the document and Mr. Kosty's unfamiliarity.
8 THE WITNESS: I would need to read this
9 document to determine the parameters around this
10 matching. If it's within a year, yes, those data
11 are going to be available and that would not
12 surprise me. But I would need to see what context
13 and how long the data matching period was from
14 this article.
15 I don't know if you want to give me a
16 minute to read it and find that information.
17 BY MR. STANOCH:
18 Q. I think it would be fair enough for us
19 to put it aside. But the question would be being
20 here now without reviewing the article more
21 closely, you can't say one way or the other
22 anything about the successful match rate reported
23 in this article?
24 MR. DORNER: Same objections as
25 previous.

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1 You can answer.
2 THE WITNESS: I would have to study this
3 article and understand the context and what were
4 the motivations of both parties, et cetera, before
5 opining on whether that could be replicated.
6 BY MR. STANOCH:
7 Q. You can put that aside.
8 You can turn to paragraph 156 of your
9 report, sir. Tell me when you're there.
10 A. Yes.
11 Q. And here, among other things, you're
12 talking about what you say are the payor mix at
13 independent pharmacies; right?
14 A. Yes.
15 Q. And then you go on in the next paragraph
16 talking about the prices paid for VCDs may be
17 different for independent pharmacies versus larger
18 chain stores pharmacy; right?
19 A. Yes. Typically, an independent pharmacy
20 is not able to negotiate as favorable
21 reimbursement rates as a large major chain.
22 Q. Does variation in the price paid for a
23 valsartan-containing drug matter in this
24 litigation for purposes of either of the two
25 economic loss classes?

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1 MR. DORNER: Object to the form to the
2 extent it's outside the scope and/or calls for a
3 legal conclusion.
4 You can answer if you know.
5 THE WITNESS: Yeah, for the TPP class,
6 it would vary on what was paid.
7 BY MR. STANOCH:
8 Q. TPP class membership is based on whether
9 they paid; right?
10 MR. DORNER: I'm sorry. I didn't catch
11 that, Dave. We had a cutout on that. Could you
12 repeat that?
13 BY MR. STANOCH:
14 Q. TPP class membership is based on whether
15 they paid or reimbursed for a drug; right?
16 MR. DORNER: Object to the
17 characterization. Legal conclusion.
18 You can answer.
19 THE WITNESS: Yes.
20 BY MR. STANOCH:
21 Q. TPP class membership does not depend on
22 the dollar amount that was reimbursed for a
23 particular drug; correct?
24 MR. DORNER: Same objection.
25 THE WITNESS: In order to calculate

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1 damages, you would need to know what that TPP paid
2 for that individual drug.
3 BY MR. STANOCH:
4 Q. We're just talking about
5 ascertainability and identification of class
6 membership now. Okay, sir?
7 A. Okay.
8 Q. And for that purpose, price variation in
9 the amounts paid or reimbursed for
10 valsartan-containing drugs doesn't matter, does
11 it?
12 MR. DORNER: Object to form. Same
13 objection.
14 THE WITNESS: No, it doesn't matter. It
15 just matters if the TPP is self-insured or fully
16 insured.
17 BY MR. STANOCH:
18 Q. If a TPP was ultimately responsible for
19 reimbursing a dollar, it falls within the class as
20 much as a TPP that would have been reimbursing a
21 thousand dollars; right?
22 MR. DORNER: Same objections.
23 You can answer.
24 THE WITNESS: Yes.
25

<p style="text-align: right;">Page 274</p> <p>1 BY MR. STANOCH: 2 Q. We're not in this case trying to 3 construct a but-for world price for valsartan, are 4 we? 5 MR. DORNER: Object to the form. Calls 6 for a legal conclusion. Vague. 7 You can answer if you understand. 8 THE WITNESS: I don't know. 9 BY MR. STANOCH: 10 Q. You're certainly not proffering any 11 opinion on what the price for valsartan-containing 12 drugs should have been in a different hypothetical 13 world, are you? 14 A. No. That was not part of my assignment. 15 Q. You can look at paragraph 161, sir. 16 Tell me when you're there. 17 A. Yes. 18 Q. Here you're talking about obtaining 19 claims data from individual TPPs; correct? 20 A. Yes. 21 Q. You're not opining, sir, that TPPs 22 cannot provide their own data to show how much 23 they ultimately paid for valsartan-containing 24 drugs, are you? 25 MR. DORNER: Object to form.</p>	<p style="text-align: right;">Page 276</p> <p>1 A. No. They could go ask their PBM or TPA, 2 yes. 3 Q. You don't offer any opinion that any TPP 4 class member could not go to its PBM, TPA, ASO to 5 obtain data on how much a given TPP reimbursed for 6 valsartan-containing drugs, are you? 7 MR. DORNER: Object to form. Asked and 8 answered. 9 You can answer. 10 THE WITNESS: I did not. 11 BY MR. STANOCH: 12 Q. You did not analyze how hard it would be 13 for any particular TPP to access their own payment 14 data to provide proof of class membership, did 15 you? 16 A. No. That was not part of my assignment. 17 Q. In fact, the only example you cite in 18 paragraph 161 was plaintiff MADA and it did go to 19 its ASO and PBM to get certain data for its 20 payment for valsartan-containing drugs; right? 21 A. Yes. 22 Q. You don't have any other specific 23 examples about TPPs and whether or not it would be 24 difficult for them or not -- strike that. 25 You don't offer in paragraph 161 or</p>
<p style="text-align: right;">Page 275</p> <p>1 You can answer. 2 THE WITNESS: They may have difficulty 3 getting that information. In this case, MADA had 4 to go to two or three entities to get that 5 information. They were the TPP, so they were able 6 to obtain that information. 7 MR. DORNER: I think the court reporter 8 might have had difficulty. Could you just repeat 9 the last part of your answer, Mr. Kosty? Never 10 mind. 11 BY MR. STANOCH: 12 Q. Sir, you're not opining that TPPs cannot 13 access records themselves showing what they paid 14 for valsartan-containing drugs, are you? 15 A. It's a little bit more complicated than 16 that. If the TPP maintains their own records, 17 then they could access them obviously. But if 18 they don't maintain their own records and they 19 have to go to their PBM or TPA to get that 20 information, then that's what they would need to 21 do. 22 Q. And are you opining that a TPP could not 23 go to its own PBM and TPA to obtain data on how 24 much the TPP reimbursed for valsartan-containing 25 drugs?</p>	<p style="text-align: right;">Page 277</p> <p>1 elsewhere any specific examples of a particular 2 TPP and whether it can or cannot obtain its own 3 reimbursement data, do you? 4 A. I do not. 5 Q. Sir, do you agree that a 6 claims -- strike that. 7 You make discussion in your report 8 throughout about TPAs and ASOs; right? 9 A. Yes. 10 Q. And we can agree TPA means third-party 11 administrator? 12 A. Yes. 13 Q. And ASO means administrative services 14 organization? 15 A. Yes. 16 Q. And I think you may mention once or 17 twice a PSAO. And what's a PSAO? 18 A. PSAO is in context to a group of 19 independent pharmacies, a pharmacy services 20 administrative organization. 21 Q. Do you offer any opinion in your report 22 that PSAOs would not have records of their own 23 pharmacy clients' transactions? 24 A. That was not part of my assignment, so I 25 didn't offer an opinion on that question.</p>

<p style="text-align: right;">Page 278</p> <p>1 Q. You're not offering any opinions, sir, 2 are you, that a TPA or ASO does not have data on 3 their respective clients' drug reimbursements? 4 MR. DORNER: Object to the 5 characterization. 6 You can answer. 7 THE WITNESS: I do not. 8 BY MR. STANOCH: 9 Q. Do you agree that the claims data that a 10 PBM presents to a TPA or ASO must be sufficient to 11 allow the TPA or ASO to bill their respective TPP 12 clients? 13 MR. DORNER: Object to form. 14 You can answer if you understand. 15 THE WITNESS: I understand, yes, in 16 terms of invoicing, perhaps in terms of detail. 17 BY MR. STANOCH: 18 Q. Do you agree that PBM data must be in a 19 format that allows a TPA or ASO to link particular 20 pharmacy claims to their respective self-funded 21 plan clients? 22 A. Could you repeat the question? 23 Q. Sure. Do you agree that PBM -- I'll 24 start over. 25 Do you agree that PBM data must be in a</p>	<p style="text-align: right;">Page 280</p> <p>1 A. Yes. 2 Q. You don't offer any opinion anywhere in 3 your report of any particular TPA or ASO that 4 simply tells a PBM just give us a bill that says 5 pay us X, do you? 6 A. I do not. 7 Q. Do you offer any opinion in your report 8 that any TPA or ASO does not have data to identify 9 its client payors? 10 MR. DORNER: Object to form. 11 You can answer. 12 THE WITNESS: Can you define client 13 payors? 14 BY MR. STANOCH: 15 Q. Sure. How would you define the entities 16 that would retain a TPA or ASO to manage pharmacy 17 benefits? 18 A. It would be the TPA's clients. So 19 you're asking that question with -- 20 Q. Yes. I'll re-ask it. 21 A. Thank you. 22 Q. Do you offer any opinion in your report 23 that any TPA or ASO does not have data to identify 24 its clients? 25 A. No.</p>
<p style="text-align: right;">Page 279</p> <p>1 format that allows a TPA or ASO to link particular 2 pharmacy claims to their respective self-funded 3 plan clients? 4 MR. DORNER: Object to form. Vague. 5 And foundation. 6 You can answer if you understand it. 7 THE WITNESS: Same as the previous 8 answer. Yes and no. It depends on what that TPA 9 requires from the PBM to bill their clients. If 10 they want the claims detail associated with it, 11 then it would be available. If they just want a 12 bill that says pay us X, that would be available, 13 too. 14 BY MR. STANOCH: 15 Q. You don't offer an opinion, do you, sir, 16 in your report as to any TPA or ASO that says just 17 send us a bill; right? 18 MR. DORNER: Object to the 19 characterization. 20 You can answer if you understand. 21 THE WITNESS: I do not. 22 BY MR. STANOCH: 23 Q. You said if you just want a bill that 24 says pay us X, that's a possibility. Is that what 25 you said?</p>	<p style="text-align: right;">Page 281</p> <p>1 Q. You mentioned in your report the 2 potential for an ASO that may contract with 3 another ASO. 4 A. Yes. 5 Q. You don't provide any analysis in your 6 report, do you, about how frequently the layering 7 of ASOs might occur, do you? 8 A. Not in that example, no. 9 Q. You did not analyze whether PBMs and any 10 TPA or ASO name their fields in their respective 11 claims data system differently, did you? 12 MR. DORNER: Object to form. 13 You can answer. 14 THE WITNESS: I did not. 15 BY MR. STANOCH: 16 Q. Would you agree that a PBM needs a PCN 17 number to process a pharmacy claim and route it to 18 the appropriate party? 19 A. No. 20 Q. What is a PCN number? 21 A. It's a processor control number. 22 Q. Did you provide any analysis in your 23 report about whether a PBM needs a PCN number to 24 process a pharmacy claim and route it to the 25 appropriate party?</p>

<p style="text-align: right;">Page 282</p> <p>1 A. I didn't provide an analysis, but I 2 provided an example. Let me find it. It was the 3 OptumRx payor sheet. 4 Q. Other than the OptumRx payor sheet that 5 you cite, did you provide any other examples? 6 A. No. I just provided that one example. 7 Once I get to it, I'll go through it with you. 8 Q. When you get to that page, let me know 9 the page first. That's the question. What page 10 is that? 11 A. That's a good question. That's what I'm 12 looking for. It is page 53 of the report. 13 Q. Are you talking about Figure 2? 14 A. Yes, that's correct. This is a sample 15 of the 2021 OptumRx payor sheet. It explains to 16 the pharmacy how to route a claim to them. And if 17 you look through here, it will tell you who the 18 client is. 19 I know ProAct, as I mentioned in the 20 report, is a PBM with a BIN and processor control 21 number. So the pharmacy needs that BIN and 22 processor control number to route claims for Optum 23 for ProAct PBM. The pharmacy has no idea who 24 ProAct PBM's customers are, nor do they 25 necessarily care. All they care is they can route</p>	<p style="text-align: right;">Page 284</p> <p>1 A. They don't route the claim back to them. 2 They bill them for the services provided. But, 3 yes, they would be able to identify who to bill 4 for those service. 5 Q. And the services we're talking about 6 would be the pharmacy benefit to cover in this 7 case valsartan-containing drugs? 8 A. Correct. 9 Q. And you would expect that to be the same 10 in the instance of MedalistRx; right? 11 A. Yes. 12 Q. Thank you. Let's switch gears a little 13 bit to a discussion about the medical monitoring 14 class, sir. 15 A. Yes. 16 Q. I think your discussion there is on 17 paragraphs 119 and 126 of your report. So why 18 don't you get there and let me know when you're 19 there. 20 A. You said 119? 21 Q. Yes, sir. 22 A. Okay. Thank you. I'm there. 23 Q. Great. And these are your opinions 24 concerning the medical monitoring class 25 specifically; right?</p>
<p style="text-align: right;">Page 283</p> <p>1 the claim, get it processed, approved for payment 2 and service their patient. 3 So in the bottom example here, it's a 4 company named MedalistRx, BIN number 016580, PCN 5 NA. It's not applicable. So this example 6 supports my industry experience that is a PCN 7 number is not required to process a pharmacy 8 claim. It's dependent upon on the claims 9 processing system and what key fields they need to 10 process the claim. 11 If you look at the NCPDP D.0 standard, 12 the PCN is an optional field. 13 Q. Do you agree that in this instance, 14 ProAct would have data to indicate which of its 15 clients it should route a particular claim back 16 to? 17 A. They would be able to bill their client 18 based on the information. If one of their clients 19 is a TPA, they would not necessarily know who that 20 TPA's client is. All they know is their 21 contractual relationship is with the TPA. 22 Q. And the question was: Do you agree that 23 ProAct would have its own data to indicate which 24 of its clients it should route a particular claim 25 back to? The answer to that is yes; right?</p>	<p style="text-align: right;">Page 285</p> <p>1 MR. DORNER: Object to form. 2 You can answer. 3 THE WITNESS: Yes. 4 BY MR. STANOCH: 5 Q. One of the first things you say in 6 paragraph 120 relates to the levels of NDMA or 7 NDEA in VCDs; right? 8 A. Yes. 9 Q. You never analyzed the levels of 10 nitrosamines in any valsartan-containing drug, did 11 you? 12 A. No. 13 Q. You never analyzed the levels of 14 nitrosamine contamination in any valsartan API, 15 did you? 16 A. No. 17 Q. You mentioned Aurobindo here 18 specifically; right? 19 A. Yes, in paragraph 120. 20 Q. Do you have any other specific examples 21 about any other defendants' valsartan-containing 22 drugs that you discuss in the context of the 23 levels of nitrosamines in their 24 valsartan-containing drugs? 25 A. No.</p>

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1 Q. Did you -- strike that.
 2 You never analyzed whether Aurobindo's
 3 lot level recalls encompassed all product lots
 4 then available on the market, did you?
 5 MR. DORNER: Object to form.
 6 THE WITNESS: No.
 7 BY MR. STANOCH:
 8 Q. Because you make it a point to say, oh,
 9 well, Aurobindo did lot level recalls; right?
 10 A. Yes.
 11 Q. But you don't know whether those lot
 12 level recalls encompassed all products from lots
 13 then available on the market at the time of the
 14 recall, did you?
 15 A. No. I did not have access to the
 16 recalled product that was obtained, no.
 17 Q. You would agree, would you, that if a
 18 lot level recall included all available lots of a
 19 given NDC, then that would effectively mean there
 20 was no product under that NDC remaining on the
 21 market?
 22 MR. DORNER: Object to form. Outside
 23 the scope. Mischaracterizes.
 24 You can answer.
 25 THE WITNESS: Yes. If they recall all

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1 lots of an NDC number, then the pharmacies would
 2 have removed those from the shelves and the
 3 wholesalers, too.
 4 BY MR. STANOCH:
 5 Q. You don't know if that occurred for
 6 Aurobindo product or not; right?
 7 A. I don't have specific examples of that
 8 occurring or not occurring, no.
 9 Q. And you don't know if that occurred for
 10 any other defendant's valsartan-containing drugs;
 11 right?
 12 A. No. I haven't seen that information.
 13 Q. As a pharmacist, do you agree that
 14 nitrosamines are carcinogenic?
 15 MR. DORNER: Object to form. Outside
 16 the scope.
 17 BY MR. STANOCH:
 18 Q. You can answer.
 19 THE WITNESS: Can I answer?
 20 MR. DORNER: Yes.
 21 THE WITNESS: I didn't know if you were
 22 done. Please repeat the question. I'm sorry.
 23 BY MR. STANOCH:
 24 Q. As a pharmacist, do you agree that
 25 nitrosamines are carcinogenic?

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1 MR. DORNER: Object to form. Outside
 2 the scope. And mischaracterizes.
 3 THE WITNESS: As a pharmacist, I don't
 4 know. I read some reports in this case both from
 5 the plaintiffs' and the defendants' clinical
 6 experts to get some background. But I haven't
 7 formed an opinion whether it's carcinogenic or
 8 not.
 9 BY MR. STANOCH:
 10 Q. As a pharmacist, do you agree that
 11 nitrosamines are genotoxic?
 12 MR. DORNER: Object to form. Same
 13 objections as my previous.
 14 THE WITNESS: Based on the clinical
 15 experts in this case, that was their contention,
 16 but I haven't independently verified it. But I
 17 assume they're right. So that's their opinion it
 18 is genotoxic.
 19 BY MR. STANOCH:
 20 Q. Were you familiar with nitrosamines from
 21 your work prior to your involvement in this case?
 22 A. Yes, only in regards to how much
 23 nitrosamines one could consume by eating a
 24 cheeseburger topped with applewood bacon and
 25 washing it down with a beer. So I am familiar

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1 that nitrosamines are available for patients to
 2 consume and they're a naturally occurring
 3 byproduct of cooked meats, smoked meats, a number
 4 of different products that do contain
 5 nitrosamines. So, yes, I was familiar with it.
 6 MR. DORNER: Mark my late objection.
 7 I'm sorry, Dave, to cut you off.
 8 BY MR. STANOCH:
 9 Q. Do you agree that any exposure to a
 10 carcinogenic substance contributes to a cancer
 11 risk?
 12 MR. DORNER: Objection to form. Lacks
 13 foundation. Outside the scope.
 14 THE WITNESS: I don't have one opinion
 15 one way or another. I'm not an epidemiologist. I
 16 don't do those kind of studies, so I don't have an
 17 opinion on it.
 18 BY MR. STANOCH:
 19 Q. You said you heard about nitrosamines
 20 with a bacon burger and a beer; right?
 21 A. Yes.
 22 Q. So as a pharmacist, do you think if that
 23 person having the bacon burger and beer also took
 24 valsartan with nitrosamines, was that valsartan
 25 additive to that person's carcinogenic risk?

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1 MR. DORNER: Object to form. I'll
2 repeat my previous objections made. Outside the
3 scope. Mischaracterizes.
4 THE WITNESS: I don't have a clinical
5 opinion on that. I don't know.
6 MS. KAPKE: This is Kara for CVS and
7 Rite-Aid. I'm just going to interpose a form
8 objection to the use of "as a pharmacist." I
9 think Mr. Kosty's report reflects his opinion in
10 this case as someone who has worked in the
11 pharmacy industry.
12 But I object to your characterization of
13 his questions starting with "as a pharmacist" when
14 they relate to these opinions that are clearly
15 outside the scope of his report.
16 MR. STANOCH: Ms. Kapke, Mr. Dorner is
17 perfectly capable of lodging objections. I'd
18 appreciate if you confined your objections to a
19 single objector. And I'll also ask him another
20 question then.
21 BY MR. STANOCH:
22 Q. Mr. Kosty, do you think that a person
23 having a bacon burger and a beer who also took
24 valsartan that contained nitrosamines -- was that
25 valsartan additive to that person's carcinogenic

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1 risk?
2 MR. DORNER: Object to form. Outside
3 the scope. Mischaracterizes. And with respect to
4 the term "as a pharmacist," object to usage of
5 that term.
6 Furthermore, other defendants have a
7 right to object on the record just as we do, and
8 that's what Ms. Kapke is going to do. She's
9 permitted to make those objections just as I am.
10 MR. STANOCH: Mr. Dorner, first of all,
11 you've said all day mischaracterizes. I'm asking
12 him the question, not his testimony. So nothing
13 is being mischaracterized. Number two, I didn't
14 use the phrase "as a pharmacist." So I don't
15 appreciate that objection.
16 BY MR. STANOCH:
17 Q. So I'm going to ask the question again,
18 sir. Mr. Kosty, do you think a person having a
19 bacon burger and a beer who also ingested
20 valsartan that had nitrosamines -- was that
21 valsartan contributive to that person's
22 carcinogenic risk?
23 MR. DORNER: Object to form. Lacks
24 foundation. Outside the scope.
25 You can answer.

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1 THE WITNESS: I don't know if it
2 increases the carcinogenic risk. I know it
3 increases the amount they consumed, but that's it.
4 BY MR. STANOCH:
5 Q. When did you first remember hearing
6 anything about nitrosamines?
7 A. I don't recall specifically. It was
8 probably related to this case though. Or in the
9 industry we get, gosh, 20, 25 news feeds to inform
10 our consultants and keep up to speed on what's
11 going on in the industry. I'm sure one of those
12 news feeds had a story about this situation.
13 Q. So it's your testimony that you never
14 knew about nitrosamines until you were retained in
15 this litigation?
16 MR. DORNER: Object to form.
17 Mischaracterizes.
18 THE WITNESS: That mischaracterizes. As
19 I mentioned, I'm sure I saw it in one of those
20 news feeds, but I don't recall the specific time
21 or date that might have happened.
22 BY MR. STANOCH:
23 Q. Those are news feeds though about this
24 litigation; right?
25 A. No. They're news feeds about the

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1 industry. Every member organization typically has
2 a news feed, some annoyingly multiple times a day.
3 I'm sure you get them, too, right. So it at least
4 informs you that there's something that perhaps
5 you need to look at. So it's just a matter of an
6 ongoing process for our consultants to stay up to
7 speed.
8 I'm sure this morning I had 20 of those
9 emails in my in-basket when I woke up.
10 Q. So sometime prior to this litigation,
11 you think you may have had a news feed that
12 discussed something about nitrosamines; fair?
13 A. Fair, yes.
14 Q. You just can't say how much before in
15 time that feed might have made it to your
16 attention?
17 MR. DORNER: Object to form.
18 You can answer.
19 THE WITNESS: I don't know.
20 BY MR. STANOCH:
21 Q. In paragraph 121 you talk about the
22 lifetime cumulative exposure threshold set forth.
23 I'm sorry. It's paragraph 119. You talk about
24 the lifetime cumulative thresholds of NDMA, NDEA
25 exposure for the medical monitoring class; is that

<p style="text-align: right;">Page 294</p> <p>1 right?</p> <p>2 A. That's correct.</p> <p>3 Q. You don't know how the lifetime</p> <p>4 cumulative exposure thresholds were established</p> <p>5 for purposes of the medical monitoring motion for</p> <p>6 class certification, do you?</p> <p>7 A. No. All I have known is what I read.</p> <p>8 It would have been interesting to see some</p> <p>9 information on how this was established, but it</p> <p>10 wasn't in the Complaint.</p> <p>11 Q. You never analyzed the lifetime</p> <p>12 cumulative exposure thresholds set forth in the</p> <p>13 medical monitoring class then; right?</p> <p>14 A. I did not.</p> <p>15 Q. You don't know, for instance, if the</p> <p>16 lifetime cumulative exposure thresholds were based</p> <p>17 on the lowest levels of nitrosamine contamination</p> <p>18 found in any particular valsartan-containing drug,</p> <p>19 do you?</p> <p>20 A. How those levels were established by the</p> <p>21 plaintiffs, I don't know how they did it, so no.</p> <p>22 Q. If the thresholds were based on the</p> <p>23 lowest documented nitrosamine levels, then your</p> <p>24 point about variations of levels you write about</p> <p>25 doesn't matter, does it?</p>	<p style="text-align: right;">Page 296</p> <p>1 analyze the nitrosamine levels any particular</p> <p>2 drug; right?</p> <p>3 A. No.</p> <p>4 Q. Your point is that they may have varied;</p> <p>5 right?</p> <p>6 A. Well, the documentation I've seen, for</p> <p>7 example, the Aurobindo you mentioned, there were</p> <p>8 variations of nitrosamine levels between lot</p> <p>9 numbers, yes.</p> <p>10 Q. If the thresholds were based on the</p> <p>11 lowest documented Aurobindo levels, then that</p> <p>12 would be the most conservative assumption?</p> <p>13 MR. DORNER: Object to form. Lacks</p> <p>14 foundation.</p> <p>15 You can answer.</p> <p>16 THE WITNESS: The assumption there is</p> <p>17 they all had impurities. I don't know if they did</p> <p>18 or not, but there could have been some lot numbers</p> <p>19 that had no detectable impurities. I don't know</p> <p>20 specifically to that level of detail without</p> <p>21 looking at documentation.</p> <p>22 BY MR. STANOCH:</p> <p>23 Q. Assume that all the given defendant</p> <p>24 manufacturers of valsartan had some level of</p> <p>25 nitrosamine in it. Okay?</p>
<p style="text-align: right;">Page 295</p> <p>1 MR. DORNER: Objection. Argumentative.</p> <p>2 Lacks foundation.</p> <p>3 THE WITNESS: No. That's incorrect. It</p> <p>4 does matter. It matters that you're able to</p> <p>5 accurately identify the amount ingested by</p> <p>6 patients over time. And part of my assignment was</p> <p>7 to opine on the ability -- and let me find it for</p> <p>8 you so I can read it.</p> <p>9 "The extent to which available data</p> <p>10 allow for the calculation of the amount of</p> <p>11 impurities to which a patient may have been</p> <p>12 exposed and the extent to which the data are</p> <p>13 available sufficiently to reliably estimate</p> <p>14 damages."</p> <p>15 So it's the amount that the patients</p> <p>16 were exposed to.</p> <p>17 BY MR. STANOCH:</p> <p>18 Q. What are you reading from?</p> <p>19 A. Paragraph 24, my assignment.</p> <p>20 Q. It's a hundred paragraphs earlier. Hold</p> <p>21 on.</p> <p>22 A. I know. So if you go four lines up from</p> <p>23 the bottom once you get there.</p> <p>24 Q. I see it. Thank you. I see it. Your</p> <p>25 point on the levels is that -- again, you didn't</p>	<p style="text-align: right;">Page 297</p> <p>1 A. Okay.</p> <p>2 Q. And if the lowest documented level of</p> <p>3 nitrosamine was used to calculate the thresholds,</p> <p>4 that would be the most conservative assumption?</p> <p>5 MR. DORNER: Object to form. Lacks</p> <p>6 foundation.</p> <p>7 You can answer.</p> <p>8 THE WITNESS: Yes. As a hypothetical,</p> <p>9 yes.</p> <p>10 BY MR. STANOCH:</p> <p>11 Q. Another opinion you have about the</p> <p>12 medical monitoring class is about actual</p> <p>13 consumption. You talk about that in paragraph</p> <p>14 122; is that right?</p> <p>15 A. Yes. That's correct. This is an area</p> <p>16 that the pharmacy industry has focused on for</p> <p>17 years to try to get patients that -- just because</p> <p>18 a prescription was dispensed to a patient doesn't</p> <p>19 mean they take the medication as prescribed.</p> <p>20 So this illustrates a study for</p> <p>21 hypertensive patients. I believe it was about</p> <p>22 70 percent of the medication that was dispensed</p> <p>23 was actually consumed in this study.</p> <p>24 Q. You're talking about the study</p> <p>25 referenced in your footnote 219, Chang, et al.?</p>

<p>Page 298</p> <p>1 A. Correct.</p> <p>2 Q. We'll mark that as the next exhibit,</p> <p>3 Exhibit 11.</p> <p>4 (Kosty Exhibit 11 was marked.)</p> <p>5 BY MR. STANOCH:</p> <p>6 Q. Tell me when you can see it, sir. I'm</p> <p>7 also sharing it.</p> <p>8 A. Okay.</p> <p>9 Q. Do you have it in front of you now, sir?</p> <p>10 A. I do.</p> <p>11 Q. And before we get into it, this is the</p> <p>12 only study that you cite specifically for your</p> <p>13 opinion in paragraph 122; right?</p> <p>14 A. That's correct.</p> <p>15 Q. Again, your opinion there is talking</p> <p>16 about actual consumption, which I take to mean</p> <p>17 someone who filled the prescription, if they</p> <p>18 actually ingested the pill; right?</p> <p>19 A. Correct.</p> <p>20 Q. You would call it nonadherence if</p> <p>21 somebody filled the script and then didn't take</p> <p>22 all of that script; right?</p> <p>23 A. Correct.</p> <p>24 Q. That's not the same type of nonadherence</p> <p>25 that the Chang article is talking about, is it?</p>	<p>Page 300</p> <p>1 the section called Calculation of Nonadherence and</p> <p>2 Prescription Fill Characteristics. Do you see</p> <p>3 that?</p> <p>4 A. What page are you on there?</p> <p>5 Q. This would be page 137.</p> <p>6 A. Okay.</p> <p>7 Q. Do you see the article writes there,</p> <p>8 "Medication nonadherence was calculated using the</p> <p>9 proportion of days covered algorithm." Is that</p> <p>10 right?</p> <p>11 A. Yes.</p> <p>12 Q. It continues, "Proportion of days</p> <p>13 covered represents the proportion of days an</p> <p>14 individual had prescription medication available</p> <p>15 from the index prescription fill date until their</p> <p>16 death or the study end date, December 31, 2015."</p> <p>17 Do you see that?</p> <p>18 A. Yes.</p> <p>19 Q. Then it continues, "Nonadherence was</p> <p>20 defined as the proportion of days covered less</p> <p>21 than 80 percent which aligns with current</p> <p>22 standards." Right?</p> <p>23 A. Yes.</p> <p>24 Q. So this article is talking about</p> <p>25 nonadherence in terms of days in which a</p>
<p>Page 299</p> <p>1 A. I'm going to have to refamiliarize</p> <p>2 myself with this article, so give me a minute.</p> <p>3 Q. While you're doing that, I'll ask a</p> <p>4 different question, sir.</p> <p>5 MR. DORNER: Then I'll move to strike</p> <p>6 the pending question.</p> <p>7 MR. STANOCH: Hold on, Mr. Dorner.</p> <p>8 Relax. I don't need a smirk either.</p> <p>9 MR. DORNER: Are you withdrawing your</p> <p>10 question?</p> <p>11 MR. STANOCH: Withdraw the prior</p> <p>12 question. I will withdraw the prior question,</p> <p>13 Mr. Dorner.</p> <p>14 MR. DORNER: Thanks.</p> <p>15 BY MR. STANOCH:</p> <p>16 Q. Mr. Kosty, have you seen this article</p> <p>17 before today?</p> <p>18 A. Yes.</p> <p>19 Q. You read it before?</p> <p>20 A. Yes.</p> <p>21 Q. When is the last time you read it?</p> <p>22 A. I looked at an excerpt of it preparing</p> <p>23 for this deposition, or a highlighted. I don't</p> <p>24 recall offhand.</p> <p>25 Q. I'm going to direct your attention to</p>	<p>Page 301</p> <p>1 prescription was in existence for a particular</p> <p>2 drug; right?</p> <p>3 A. Yes.</p> <p>4 Q. This article is not talking about</p> <p>5 nonadherence in terms of whether a particular</p> <p>6 patient actually ingested any pill that they got</p> <p>7 from a dispensed product; right?</p> <p>8 MR. DORNER: Object to the</p> <p>9 characterization of the document.</p> <p>10 You can answer.</p> <p>11 THE WITNESS: Where are you reading that</p> <p>12 from, counselor?</p> <p>13 BY MR. STANOCH:</p> <p>14 Q. I'm asking. We established here that</p> <p>15 nonadherence, as this article defines it, means</p> <p>16 days in which a prescription was not available to</p> <p>17 cover those dates; right?</p> <p>18 A. Yeah. Proportion of days covered</p> <p>19 measures the prescription available to a patient</p> <p>20 that hasn't been taken.</p> <p>21 Q. Right. So, for instance, if someone got</p> <p>22 a 30-day prescription, stopped for 30 days and</p> <p>23 then got another prescription for the next 30</p> <p>24 days, in that 90-day period, days covered would be</p> <p>25 60 out of 90; right?</p>

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<p>1 A. Correct.</p> <p>2 Q. And nonadherence in that instance for</p> <p>3 how this articles defines nonadherence would be 30</p> <p>4 days out of that 90-day period; right?</p> <p>5 A. In that example, yes.</p> <p>6 Q. So that type of nonadherence is</p> <p>7 different than what you're talking about in terms</p> <p>8 of whether someone actually ingests the pills in a</p> <p>9 prescription bottle they get from a pharmacy;</p> <p>10 right?</p> <p>11 A. Right. But let's go back to the metric.</p> <p>12 This metric doesn't measure whether patients have</p> <p>13 taken that medication or not. All we know in your</p> <p>14 example there's a prescription that was refilled</p> <p>15 twice in the 90-day period. And for 30 days we're</p> <p>16 assuming they didn't take that medication, right.</p> <p>17 But we don't know. We don't know if they had a</p> <p>18 supplier medication, that they took those or they</p> <p>19 didn't take it.</p> <p>20 So this is the measurement that's used</p> <p>21 in the industry to calculate nonadherence and</p> <p>22 determine in this example that the patient was not</p> <p>23 taking their medication for the 30 days. In fact,</p> <p>24 CMS uses a similar metric for the Medicare Part D</p> <p>25 Star Ratings to measure this rate of adherence.</p>	<p>1 think it's proportion -- but anyway, you have to</p> <p>2 look at how much was available for that patient to</p> <p>3 take. Then you track them longitudinally over</p> <p>4 time to see how much they actually took based on</p> <p>5 the claims data. And then making that use of</p> <p>6 data, that's how you determine the nonadherence</p> <p>7 rate like they did here.</p> <p>8 That's exactly how the industry does it,</p> <p>9 and those are the determinations made on those.</p> <p>10 So when Medicare Part D implemented these Star</p> <p>11 Ratings, all Medicare Part D plans were incented</p> <p>12 to work with patients to try to get their</p> <p>13 adherence rates up. And they got bonuses for</p> <p>14 improving those metrics.</p> <p>15 So one easy way to improve the metric is</p> <p>16 to convert people to mail service, right. So</p> <p>17 instead of having to fill 12 prescriptions per</p> <p>18 year for a maintenance drug, you only need to fill</p> <p>19 four prescriptions a year for the maintenance</p> <p>20 drug. So immediately upon that change, at least</p> <p>21 for the first quarter, you've increased that</p> <p>22 patient's compliance rate because they have that</p> <p>23 90-day supply in their possession.</p> <p>24 Then you would have to look at when they</p> <p>25 got their next refill in my mail service example</p>
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<p>1 So it's a standard measurement in the industry.</p> <p>2 Q. In fact, this article assumes, does it</p> <p>3 not, that a patient took all of the pills for a</p> <p>4 given prescription that he or she received;</p> <p>5 correct?</p> <p>6 MR. DORNER: Object to the</p> <p>7 characterization.</p> <p>8 You can answer if you know.</p> <p>9 THE WITNESS: Yes. That's the only</p> <p>10 assumption you can make, because no one knows. No</p> <p>11 one is at that patient's house watching them</p> <p>12 whether or not they take the medication or not.</p> <p>13 So when you're looking at claims data or pharmacy</p> <p>14 data, those are the things that are implied in</p> <p>15 these calculations.</p> <p>16 BY MR. STANOCH:</p> <p>17 Q. So again, the Chang article's discussion</p> <p>18 of nonadherence relates to days during a given</p> <p>19 period of time where there that was not a</p> <p>20 prescription available for a drug; right?</p> <p>21 MR. DORNER: Object to form.</p> <p>22 THE WITNESS: A prescription was</p> <p>23 available, but the medication was not taken. So</p> <p>24 without getting into the specific calculations of</p> <p>25 percentage of days covered or proportion -- I</p>	<p>1 to determine if they're taking it and ingesting it</p> <p>2 as prescribed by the physician. So, yeah, the</p> <p>3 claims data is all we have to do these</p> <p>4 calculations, and this is the industry standard</p> <p>5 for how to do it.</p> <p>6 BY MR. STANOCH:</p> <p>7 Q. In paragraph 123 you talk about</p> <p>8 combining data records; is that right?</p> <p>9 A. Yes, a consumption record for individual</p> <p>10 consumers.</p> <p>11 Q. You're aware that the retailer pharmacy</p> <p>12 defendants in this case along with Humana Pharmacy</p> <p>13 produced data for individual consumers of</p> <p>14 valsartan prescriptions; right?</p> <p>15 MR. DORNER: Object to form.</p> <p>16 You can answer.</p> <p>17 THE WITNESS: Yes.</p> <p>18 BY MR. STANOCH:</p> <p>19 Q. You performed no analysis, did you, to</p> <p>20 test whether pharmacy data could not be combined</p> <p>21 to track a patient's drug usage across multiple</p> <p>22 pharmacies, did you?</p> <p>23 A. I did not. That was not part of my</p> <p>24 assignment.</p> <p>25 Q. And because you never analyzed that, you</p>

<p>Page 306</p> <p>1 cannot say and do not offer an opinion how long it 2 would take to construct such a record; correct? 3 A. I did not offer that opinion, no. 4 Q. In fact, you never even looked at all 5 the retail pharmacy defendants' data that they 6 produced in this case, did you? 7 MR. DORNER: Object to form. 8 You can answer if you know. 9 THE WITNESS: I did not. 10 BY MR. STANOCH: 11 Q. In your discussion of the medical 12 monitoring class here, you're also presuming that 13 it's going to be necessary to combine pharmacy 14 data in the first place, aren't you? 15 A. That's one of the assumptions, yes. So 16 if you have a patient that goes to Walgreens and 17 then transfers their prescriptions to CVS and then 18 eventually to Rite-Aid, you would have to track 19 those patients across those pharmacies to identify 20 what their cumulative lifetime consumption of 21 those products were. 22 The challenge is how do you track those 23 patients across the different pharmacy datasets. 24 As I indicate in my report, there's no universal 25 patient identifier that allows one to track those</p> <p>Page 307</p> <p>1 patients. So each pharmacy system assigns a 2 unique patient identification number that enables 3 that chain to track the patient. That number is 4 unique to the chain and it doesn't vary -- it does 5 vary between chains. 6 So when you say I'll need to track that 7 patient, well, if they've only gone to Walgreens, 8 you can track that patient. But if they switch 9 pharmacies, maybe they went to an independent 10 pharmacy, then that information would not be even 11 available today based on what data was presented. 12 So, no, you can't track patients across 13 pharmacies in the data to determine the lifetime 14 cumulative threshold. 15 Q. Because you did not look at all at least 16 the retail pharmacies' data they produced in this 17 case, you have no opinion on how frequently it may 18 be that patients switched between pharmacies? 19 A. I didn't do a study of this data, but 20 based on my experience working with pharmacies and 21 pharmacists, it's gotten to be even more frequent 22 now to change pharmacies because people -- for 23 example, if you have after high deductible health 24 plan and your pharmacy benefit -- you have a 25 \$5,000 deductible, that patient knows for the most</p>	<p>Page 308</p> <p>1 part unless I'm on a specialty medication, I'm not 2 going to meet my deductible. 3 So they, in fact, have adopted cash 4 customer behaviors in the marketplace to shop for 5 the lowest prescription. I'm sure if you've 6 watched any TV or listened to the radio or 7 Pandora, GoodRx is advertising everywhere, right. 8 So we can save you money. The GoodRx app requires 9 you to go to the pharmacy of their choice that 10 they've identified as having a lower price. 11 So, yes, there's a tremendous amount of 12 pharmacy shopping. Quite frankly, from a clinical 13 perspective, it's detrimental to the patient 14 because no one pharmacy has all their records. 15 Q. You don't offer any opinion in your 16 report, Mr. Kosty, as to how many patients would 17 satisfy the lifetime cumulative exposure 18 thresholds based solely on a single pharmacy's 19 records, do you? 20 A. No. That was not part of my assignment. 21 Q. And because you didn't even look at all 22 the retail pharmacies' data that they produced in 23 this case, you can't tell us how hard or easy it 24 would be to combine that data, can you? 25 A. No. I haven't looked at those specific</p> <p>Page 309</p> <p>1 datasets. 2 Q. And you don't offer that opinion in your 3 report, do you? 4 A. I don't. 5 Q. On this topic, you mentioned date of 6 birth. Let's say a patient goes to one pharmacy 7 and they record their date of birth, the year, 8 just the last two digits, say birthday January 15, 9 '90. Okay? Are you with me? 10 A. You broke up a little bit. January 15, 11 1990? 12 Q. Correct. But their data only looked at 13 the last two digits. So it would be 011590. Are 14 you with me? 15 A. Okay. 16 Q. Now, let's say that patient goes to 17 another pharmacy, and they have a four digit for 18 the year, right. So the patient's birth date 19 there is 01151990. Okay? 20 A. Okay. 21 Q. Is it your position that it is not 22 administratively feasible to identify that 23 patient's prescriptions in those two pharmacies 24 because some manual review would be necessary to 25 reconcile the year values?</p>
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<p style="text-align: right;">Page 310</p> <p>1 MR. DORNER: Object to form. Incomplete 2 hypothetical. Calls for a legal conclusion. 3 You can answer. 4 THE WITNESS: Yeah, the pharmacies 5 typically do have four-digit year numbers, so that 6 wouldn't be an issue. But if not, you would have 7 to assume, and especially older people, someone is 8 over 85 years old or 80 years old, maybe older 9 than that. You would have to make some 10 assumptions. But you could get a good first pass 11 and then look at exceptions. 12 BY MR. STANOCH: 13 Q. And that's part of sort of the normal 14 data analysis in the field in which you work; 15 right? 16 A. Yeah. It's part of the manual review 17 required. 18 Q. It's your opinion though that that 19 manual review, to reconcile a date of '90 versus 20 1990, would render identification of class members 21 not administratively feasible? 22 MR. DORNER: Object to form. Calls for 23 a legal conclusion. Incomplete hypothetical. 24 But you can answer. 25 THE WITNESS: It mischaracterizes my</p>	<p style="text-align: right;">Page 312</p> <p>1 data sources. What if you have a hundred or 2 hundreds of data sources that have to be combined. 3 So you multiple that exercise by 50 or a 4 hundredfold. And then it does become 5 administratively not feasible to do this. 6 BY MR. STANOCH: 7 Q. You never did that analysis and don't 8 offer an opinion, do you, Mr. Kosty, as to at what 9 point would that analysis become administratively 10 feasible? Do you? 11 MR. DORNER: Same objection. 12 You can answer. 13 THE WITNESS: I did not offer that 14 analysis. Neither did Ms. Craft. 15 BY MR. STANOCH: 16 Q. You talk in paragraphs 137, 139 about 17 the class exclusion for defendants' employees; is 18 that right? 19 A. Yes. 20 Q. And with respect to that exclusion, you 21 list it there in paragraph 137; right? First 22 sentence. 23 A. Yes. 24 Q. And you're quoting Ms. Craft in part 25 where it says, "Defendants and affiliated entities</p>
<p style="text-align: right;">Page 311</p> <p>1 report. The date of birth is one example that 2 you're focused on here. The others are the 3 patient's name, the patient address. Those are 4 the components that are confounding in trying to 5 match up the patient information as well as the 6 identifier within that specific pharmacy system. 7 BY MR. STANOCH: 8 Q. I think we touched on this before, but 9 we'll be clear. You don't offer any opinions in 10 your report, do you, about how much, quote, manual 11 effort would be required to reconcile data in 12 different sources; correct? 13 MR. DORNER: Object to form. Asked and 14 answered. 15 THE WITNESS: That was not my 16 assignment, no. 17 BY MR. STANOCH: 18 Q. And simply because a human being may 19 have to reconcile two sets of data, does that 20 render identification of class members not 21 administratively feasible? 22 MR. DORNER: Object to form. Calls for 23 a legal conclusion. 24 THE WITNESS: Yeah, you've 25 mischaracterized it. You're talking about two</p>	<p style="text-align: right;">Page 313</p> <p>1 and their employees, officers, directors and 2 agents"; right? 3 A. Yes. 4 Q. And the only portion of that exclusion 5 you're focused on is defendants' employees as you 6 state; correct? 7 A. Correct. 8 Q. You're not offering any opinions on 9 whether it would be challenging or not 10 administratively feasible to identify defendants' 11 affiliate entities; right? 12 MR. DORNER: Object to form. Legal 13 conclusion. 14 You can answer. 15 THE WITNESS: Well, it depends on how 16 you define affiliated entities. So in the example 17 in the case today, we have Express Scripts and 18 Cigna are owned by the same entity. I would 19 consider both sets of patients part, or employees, 20 of that entity. 21 BY MR. STANOCH: 22 Q. In terms of -- I'm sorry. Are you done? 23 A. Yeah. I'm just saying a lot of these 24 companies have -- you might say, well, it's 25 Amerisource Bergen, but they might have 30 or 50</p>

<p>Page 314</p> <p>1 subsidiaries that they own and manage under that 2 corporate umbrella. 3 So when I state employees, it would 4 include not only ABC corporate, but all their 5 affiliates and subsidiaries to evaluate. 6 Q. You're not offering any opinion on 7 whether it would be challenging or not to identify 8 a defendant's affiliate entities, are you? 9 A. No. 10 Q. You're focused purely on human beings, 11 not entities; right? 12 A. Correct. 13 Q. Employees; right? 14 A. Employees. 15 MR. DORNER: Object to form. 16 You can answer. 17 BY MR. STANOCH: 18 Q. I don't think you are, but let's make it 19 clear. You're not opining that the defendants in 20 this case do not maintain records of who their 21 employees are, are you? 22 A. No, I'm not. 23 Q. Did you ask any defendant in this case 24 whether they keep records of their employees? 25 A. I did not.</p>	<p>Page 316</p> <p>1 THE WITNESS: I don't know. I would not 2 think so, but I don't know. 3 BY MR. STANOCH: 4 Q. You're not offering that opinion here; 5 right? 6 A. I'm not, no. 7 Q. And you're not offering any opinion on 8 how frequently this same exclusion appears in 9 other class cases, are you? 10 A. No. 11 Q. And the numbers of employees you list in 12 your Table 3, you agree those are numbers you 13 pulled from publicly-available information? 14 A. Yes. 15 Q. And those are numbers concerning the 16 entire United States; right? 17 A. It would be numbers of employees 18 employed by these entities. I have no idea. 19 Assuming if they're global, maybe it's included. 20 I don't know. 21 Q. You understand that the class 22 definitions here encompass less than all 50 states 23 of the country; right? 24 A. Yes. 25 Q. Did you do any analysis whatsoever to</p>
<p>Page 315</p> <p>1 Q. Did anyone provide you any information 2 suggesting any defendant in this case did not keep 3 required records for their employees? 4 A. I did not ask for that information nor 5 ask the question, no. 6 Q. And it's certainly not referenced 7 anywhere in your report any such information; 8 right? 9 A. Correct. 10 Q. You did not look at any defendants' 11 employment records to determine how many employees 12 they may have during the class period; right? 13 A. No. We looked at publicly-available 14 information that's summarized in Table 3. 15 Q. But you didn't look at the defendants' 16 employment records such as W-2s or anything else, 17 did you? 18 A. That was not part of my assignment, no. 19 Q. And you're not opining that any 20 defendant affirmatively deleted records that would 21 show their employees during the class period, are 22 you? 23 MR. DORNER: Object to form. Calls for 24 speculation. 25 You can answer.</p>	<p>Page 317</p> <p>1 try to identify how many employees each defendant 2 had in a given state during the class period? 3 A. No. That was not part of my assignment. 4 Q. Did you do any analysis of how many 5 defendants' employees might have filled 6 prescriptions for at-issue valsartan during the 7 class period? 8 A. No. That was not part of my assignment. 9 Q. Are you offering any opinion on how much 10 effort it would take any defendant to produce its 11 own employee records to identify its employees 12 during the class period? 13 MR. DORNER: Object to form. 14 You can answer. 15 THE WITNESS: No. 16 BY MR. STANOCH: 17 Q. Let's flip back a few pages to around 18 paragraphs 128 to 136. Tell me when you're there, 19 sir. 20 MR. DORNER: Dave, we're at about an 21 hour. So I don't know what a good stopping point 22 is. 23 THE WITNESS: Can we take a quick 24 five-minute break? 25 MR. DORNER: Mr. Kosty has asked for a</p>

<p>Page 318</p> <p>1 quick five.</p> <p>2 MR. STANOCH: Fine. We can go off the</p> <p>3 record. We'll come back at 5:25.</p> <p>4 THE VIDEOGRAPHER: Off the record at</p> <p>5 5:18.</p> <p>6 (Recess from 5:18 p.m. to 5:28 p.m.)</p> <p>7 THE VIDEOGRAPHER: Back on the record at</p> <p>8 5:28.</p> <p>9 MR. DORNER: We're back on.</p> <p>10 MR. STANOCH: Thank you.</p> <p>11 BY MR. STANOCH:</p> <p>12 Q. Welcome back, Mr. Kosty. Other than</p> <p>13 your counsel, did you communicate with anyone else</p> <p>14 during the break?</p> <p>15 A. No.</p> <p>16 Q. Did you look at any documents during the</p> <p>17 break?</p> <p>18 A. No.</p> <p>19 Q. Let's turn to paragraphs 128 to 136 of</p> <p>20 your report, please. Tell me when you're there.</p> <p>21 A. I'm there.</p> <p>22 Q. Wonderful. This is where you talk about</p> <p>23 exclusion of state government entities from the</p> <p>24 TPP class; correct?</p> <p>25 A. Yes.</p>	<p>Page 320</p> <p>1 entity?</p> <p>2 A. Yes.</p> <p>3 Q. You're aware that the Patrolmen's</p> <p>4 Benevolent Association of New York is a city level</p> <p>5 organization?</p> <p>6 MR. DORNER: Object to form.</p> <p>7 Characterization.</p> <p>8 THE WITNESS: Yes.</p> <p>9 BY MR. STANOCH:</p> <p>10 Q. You said "yes"?</p> <p>11 A. Yes. I looked at it one time. I</p> <p>12 couldn't tell you what the city was, but, yes, I</p> <p>13 looked at this.</p> <p>14 Q. It's probably New York City; is that</p> <p>15 fair?</p> <p>16 MR. DORNER: Same objection.</p> <p>17 You can answer.</p> <p>18 THE WITNESS: Yes. I would expect it,</p> <p>19 yes.</p> <p>20 BY MR. STANOCH:</p> <p>21 Q. And as a city, state government entity,</p> <p>22 it's proper, is it not, to include it as Dr. Conti</p> <p>23 did; correct?</p> <p>24 MR. DORNER: Object to form. Calls for</p> <p>25 a legal conclusion.</p>
<p>Page 319</p> <p>1 Q. And you provide certain examples in this</p> <p>2 section; correct?</p> <p>3 A. Yes.</p> <p>4 Q. One of them in paragraph 130 is that of</p> <p>5 the New York State Nurses Association and the</p> <p>6 Patrolmen's Benevolent Association; right?</p> <p>7 A. Correct.</p> <p>8 Q. And you write at the end Dr. Conti</p> <p>9 excluded New York State Nurses Association; right?</p> <p>10 A. Yes.</p> <p>11 Q. You'd agree that exclusion would be</p> <p>12 correct though because that would be a state</p> <p>13 government entity; right?</p> <p>14 MR. DORNER: Objection. Lacks</p> <p>15 foundation.</p> <p>16 You can answer.</p> <p>17 THE WITNESS: Yes. They should be</p> <p>18 excluded.</p> <p>19 BY MR. STANOCH:</p> <p>20 Q. And you say she includes Patrolmen's</p> <p>21 Benevolent Association of New York; right?</p> <p>22 A. Yes.</p> <p>23 Q. And it's your contention that</p> <p>24 Patrolmen's Benevolent Association of New York</p> <p>25 should have been excluded as a state government</p>	<p>Page 321</p> <p>1 You can answer.</p> <p>2 THE WITNESS: As long as it's a</p> <p>3 self-funded plan, yes.</p> <p>4 BY MR. STANOCH:</p> <p>5 Q. Well, the point here is about exclusion</p> <p>6 of state government entities; right?</p> <p>7 A. Yes.</p> <p>8 Q. And city and county governments were not</p> <p>9 part of that; right?</p> <p>10 A. Well, it depends how you define state</p> <p>11 government entities.</p> <p>12 Q. Well, it's defined in the class</p> <p>13 definition for the TPPs. You remember that;</p> <p>14 right?</p> <p>15 A. Okay.</p> <p>16 Q. I'm sorry. What was the answer?</p> <p>17 A. Yes.</p> <p>18 Q. So if the Patrolmen's Benevolent</p> <p>19 Association of New York is a city government</p> <p>20 entity, then it's proper to include it as</p> <p>21 Dr. Conti did; right?</p> <p>22 MR. DORNER: Repeat my objections.</p> <p>23 THE WITNESS: If it's a city-based</p> <p>24 organization.</p> <p>25</p>

<p>Page 322</p> <p>1 BY MR. STANOCH: 2 Q. You didn't offer any analysis that you 3 did here to confirm whether Patrolmen's Benevolent 4 Association of New York is a city government 5 entity that should be included; right? 6 A. I did not. 7 Q. If you jump down to paragraph 132, you 8 talk about Montana; correct? 9 A. Yes. 10 Q. I think you say that Montana considers 11 the Montana University System employees to be 12 state employees; right? 13 A. Yes. 14 Q. And you cite an article from a local 15 Montana paper. 16 A. What footnote are you referring to? 17 Q. I'm looking at footnote 244 in paragraph 18 133, sir. 19 A. Yes. It is from a Montana paper. 20 Q. That article doesn't say anything about 21 the pharmacy benefit plan, does it. 22 A. I would have to refer to that article to 23 answer your question. 24 Q. I'll pull it up. Did you look at that 25 article prior to today?</p> <p>Page 323</p> <p>1 A. Yes. 2 MR. DORNER: Object to form. 3 You can answer. 4 THE WITNESS: Yes. 5 (Kosty Exhibit 12 was marked.) 6 BY MR. STANOCH: 7 Q. Here's Exhibit 12. Let me know when you 8 can access it. I'm sharing my screen as well. Do 9 you see it? 10 A. I'm bringing it up. 11 Q. Do you have it? 12 A. I do have it up. I'm reading through 13 it. Okay. 14 Q. This article is talking about the 15 salaries of certain folks; right? 16 A. At the start of it it does, yes. 17 Q. It doesn't talk anything about the 18 pharmacy benefit plan for any particular 19 employees, does it? Sir? 20 A. I'm sorry. I was looking through it. I 21 do not see that reference, no. 22 Q. There's no discussion about whether the 23 Montana University System's prescription drug plan 24 is self-funded or not, is there? 25 A. There is not.</p>	<p>Page 324</p> <p>1 Q. Did you think to go to anything publicly 2 available from the State of Montana to confirm 3 your assertion that Montana University System is 4 not self-funded? 5 A. I did not. 6 Q. I'm going to mark the next exhibit, 7 Exhibit 13. 8 (Kosty Exhibit 13 was marked.) 9 BY MR. STANOCH: 10 Q. The title page, it reads Montana 11 University System Summary Plan Description 12 Effective July 1, 2021. Do you see that? 13 A. I do. 14 Q. Have you seen this document before? 15 A. No. 16 Q. In the plan funding section, it says, 17 "The Montana University System medical plan, 18 prescription drug plan, dental plans and the 19 vision hardware plans are self-insured, 20 self-funded." 21 Do you see that? 22 MR. DORNER: I'll object to form. This 23 is a document from 2021. It doesn't cover the 24 claim period. I'll further object that this is a 25 112-page document that Mr. Kosty has never before</p> <p>Page 325</p> <p>1 seen. With that noted -- 2 MR. STANOCH: Noted. 3 BY MR. STANOCH: 4 Q. Do you see that you language, Mr. Kosty? 5 A. Yes. 6 Q. That would suggest, would it not, that 7 the prescription drug plan for Montana University 8 System employees is self-funded; right? 9 MR. DORNER: Same objections. 10 THE WITNESS: Yeah, for benefits 11 effective July 1, 2021, yes. 12 BY MR. STANOCH: 13 Q. Right. You didn't go ahead and conduct 14 any analysis to see how easily one could look up 15 your assertion which you cited the newspaper 16 article for that the Montana University System 17 would not be self-funded? 18 MR. DORNER: Objection. Unintelligible 19 question. 20 THE WITNESS: What I would do is go back 21 through the class period from 2012 forward to look 22 at SPD if it was available to make that 23 determination. 24 BY MR. STANOCH: 25 Q. And you didn't do that, did you?</p>
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<p>Page 326</p> <p>1 A. I did not, no.</p> <p>2 Q. And are you aware that Montana maintains</p> <p>3 a publicly-available list of self-insured plans</p> <p>4 that operate within the state?</p> <p>5 A. No.</p> <p>6 Q. You never conducted any analysis of</p> <p>7 whether Montana or any other state maintains</p> <p>8 publicly-available information about self-insured</p> <p>9 plans that operate within their borders, did you?</p> <p>10 A. No. That was not part of my assignment.</p> <p>11 Q. So you can't really say one way or the</p> <p>12 other how burdensome it would be to look up</p> <p>13 publicly-available sources to determine whether</p> <p>14 certain plans are self-funded or not from state</p> <p>15 sources; right?</p> <p>16 A. Well, this is one example of a paper</p> <p>17 document you would have to obtain and review. If</p> <p>18 you had to do that same thing for every</p> <p>19 state-funded employee group, then that could be</p> <p>20 burdensome, if you had to do that for all 50</p> <p>21 states, without looking at those self-funded</p> <p>22 websites and whether you could download</p> <p>23 information that was usable. You would have to go</p> <p>24 through a manual review assuming that's not</p> <p>25 downloadable to do that analysis.</p> <p>Page 327</p> <p>1 But I have not looked at that and would</p> <p>2 need to do that to opine further.</p> <p>3 BY MR. STANOCH:</p> <p>4 Q. You did not contact any state to verify</p> <p>5 any information about the status of their plans as</p> <p>6 self-funded or not, did you?</p> <p>7 A. No. That was not my assignment.</p> <p>8 Q. So you can't quantify for us how much</p> <p>9 time it would take to do that; correct?</p> <p>10 A. That was not my assignment. And in</p> <p>11 Ms. Craft's report, she did not undertake a</p> <p>12 similar exercise to determine how burdensome it</p> <p>13 would be or not, no.</p> <p>14 Q. That's not my question, sir. I'm asking</p> <p>15 what you did.</p> <p>16 Am I correct that you can't quantify for</p> <p>17 us how much time it would take to contact each</p> <p>18 state to determine the status if the plan is</p> <p>19 self-funded or not?</p> <p>20 MR. DORNER: Objection. Asked and</p> <p>21 answered.</p> <p>22 THE WITNESS: I did not undertake that</p> <p>23 analysis, no.</p> <p>24 BY MR. STANOCH:</p> <p>25 Q. So you can't quantify for us how much</p>	<p>Page 328</p> <p>1 time it would take to contact each state to</p> <p>2 determine the status if the plan is self-funded or</p> <p>3 not; right?</p> <p>4 MR. DORNER: Objection for the third</p> <p>5 time. Asked and answered.</p> <p>6 THE WITNESS: No. That was not part of</p> <p>7 my assignment.</p> <p>8 BY MR. STANOCH:</p> <p>9 Q. Sitting here today, could you quantify</p> <p>10 for me how much time it would take to contact each</p> <p>11 state to determine the status if the plan is</p> <p>12 self-funded or not?</p> <p>13 A. That was not part of my assignment. It</p> <p>14 would probably take a tremendous effort to go</p> <p>15 through all 50 states and analyze that.</p> <p>16 Plaintiffs have not done that to indicate their</p> <p>17 analysis of how burdensome this is in order to</p> <p>18 contact 50 states.</p> <p>19 I know from my work in the pharmacy</p> <p>20 industry, working with -- trying to get ahold of</p> <p>21 people at state is very difficult. But I have not</p> <p>22 undertaken that analysis, no.</p> <p>23 Q. You're offering no opinion in this case,</p> <p>24 are you, Mr. Kosty, about how much burden would</p> <p>25 become too much burden for purposes of verifying</p> <p>Page 329</p> <p>1 which plans states consider self-funded or not;</p> <p>2 correct?</p> <p>3 MR. DORNER: Object to form. Vague. To</p> <p>4 the extent it calls for a legal conclusion also.</p> <p>5 You can answer.</p> <p>6 THE WITNESS: No. I did not undertake</p> <p>7 that exercise.</p> <p>8 BY MR. STANOCH:</p> <p>9 Q. Would an hour be burdensome?</p> <p>10 MR. HONIK: Same objections.</p> <p>11 THE WITNESS: No. For all 50 states?</p> <p>12 If you can do that in an hour, no, that would not</p> <p>13 be burdensome.</p> <p>14 BY MR. STANOCH:</p> <p>15 Q. Would five hours be burdensome?</p> <p>16 MR. DORNER: Same objection.</p> <p>17 THE WITNESS: No. Five hours would not</p> <p>18 be burdensome.</p> <p>19 BY MR. STANOCH:</p> <p>20 Q. Would 15 hours be burdensome?</p> <p>21 MR. DORNER: Same objections.</p> <p>22 THE WITNESS: No.</p> <p>23 BY MR. STANOCH:</p> <p>24 Q. Would 25 hours be burdensome?</p> <p>25 A. No, but no one knows sitting here today</p>
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<p style="text-align: right;">Page 330</p> <p>1 how long it would take.</p> <p>2 Q. You can't tell me at what point the</p> <p>3 number of hours it would take to do this exercise</p> <p>4 becomes burdensome, can you?</p> <p>5 MR. DORNER: Same objections as the ones</p> <p>6 I stated two questions ago.</p> <p>7 THE WITNESS: That was not my</p> <p>8 assignment, no.</p> <p>9 BY MR. STANOCH:</p> <p>10 Q. Put that aside, sir. Stand by. Go to</p> <p>11 paragraph 115, sir.</p> <p>12 A. One one five, is that it?</p> <p>13 Q. Yes, sir.</p> <p>14 A. Okay.</p> <p>15 Q. Here you're talking about Ms. Craft and</p> <p>16 Dr. Conti's use of the Xponent data; right?</p> <p>17 A. Yes.</p> <p>18 Q. And you say that Dr. Conti included</p> <p>19 certain payors in her damages calculations; right?</p> <p>20 A. Yes.</p> <p>21 Q. And that Ms. Craft excluded for purposes</p> <p>22 of her counting TPPs some of those same payors in</p> <p>23 the IQVIA data; right?</p> <p>24 A. Yes.</p> <p>25 Q. The data that both Ms. Craft and</p>	<p style="text-align: right;">Page 332</p> <p>1 BY MR. STANOCH:</p> <p>2 Q. We're not talking about who, Mr. Kosty.</p> <p>3 We're talking about the amounts paid for valsartan</p> <p>4 drugs; right?</p> <p>5 A. Well, if you use that logic, then you</p> <p>6 would not have excluded anybody in the IQVIA data,</p> <p>7 right.</p> <p>8 Q. We're indicating here that Dr. Conti</p> <p>9 included payments by third-party entities</p> <p>10 reflected in the third party unspec and all other</p> <p>11 third-party fields; right?</p> <p>12 A. Yes.</p> <p>13 Q. And those fields indicate that there</p> <p>14 were payors who paid for at-issue valsartan during</p> <p>15 the class period; right?</p> <p>16 MR. DORNER: Object to form.</p> <p>17 You can answer.</p> <p>18 THE WITNESS: Based on IQVIA's</p> <p>19 definition, they don't know who paid for them.</p> <p>20 The payment was made, but they don't know who.</p> <p>21 BY MR. STANOCH:</p> <p>22 Q. Payment was paid; correct?</p> <p>23 A. Payment was made by someone.</p> <p>24 Q. Exactly. And, therefore, the fact that</p> <p>25 there was payment for at-issue valsartan is</p>
<p style="text-align: right;">Page 331</p> <p>1 Dr. Conti were looking at, they show that some</p> <p>2 entity paid something for valsartan; right?</p> <p>3 MR. DORNER: Object to form.</p> <p>4 You can answer.</p> <p>5 THE WITNESS: Yeah, third party</p> <p>6 unspecified, yes, there is data that says someone</p> <p>7 paid for it. We just don't know who paid for it.</p> <p>8 BY MR. STANOCH:</p> <p>9 Q. Right. So for Ms. Craft's purpose of</p> <p>10 identifying a particular TPP, it's appropriate to</p> <p>11 not count those folks because you don't know who</p> <p>12 they are particularly; right?</p> <p>13 A. Right. I would not have counted them in</p> <p>14 my analysis for either Craft or Conti.</p> <p>15 Q. For Dr. Conti though, the fact that</p> <p>16 someone paid for the valsartan, that's properly</p> <p>17 included in the damages estimate for the class;</p> <p>18 correct?</p> <p>19 MR. DORNER: Object to form. Outside</p> <p>20 the scope. Calls for a legal conclusion.</p> <p>21 THE WITNESS: I would disagree with</p> <p>22 that. IQVIA that you said earlier is the gold</p> <p>23 standard of pharmacy data doesn't know who these</p> <p>24 payors are. So I don't know how Ms. Conti or</p> <p>25 Dr. Conti can identify who those payors are.</p>	<p style="text-align: right;">Page 333</p> <p>1 pertinent to the total amount of damages paid</p> <p>2 regardless of identity during the class period;</p> <p>3 correct?</p> <p>4 MR. DORNER: Object to form. Lacks</p> <p>5 foundation. Outside the scope. Calls for a legal</p> <p>6 conclusion.</p> <p>7 THE WITNESS: If you would take that</p> <p>8 tact, I don't know how you would apply class</p> <p>9 exclusions to that data.</p> <p>10 BY MR. STANOCH:</p> <p>11 Q. We're not talking about exclusions here.</p> <p>12 You don't talk about that, do you, as to</p> <p>13 Dr. Conti?</p> <p>14 A. No.</p> <p>15 Q. And I think we talked about this this</p> <p>16 morning. You didn't perform any econometric</p> <p>17 analysis of the IQVIA data, did you?</p> <p>18 A. No.</p> <p>19 Q. I'm going to mark another exhibit, sir.</p> <p>20 Stand by.</p> <p>21 (Kosty Exhibit 14 was marked.)</p> <p>22 BY MR. STANOCH:</p> <p>23 Q. Sir, Exhibit 14 is the collection of</p> <p>24 invoices for your and AG's work in this case.</p> <p>25 Tell me when you have that in front of you.</p>

<p>Page 334</p> <p>1 A. Yes, I have it.</p> <p>2 Q. Are there any other invoices that have</p> <p>3 been issued for your and AG's work in this case</p> <p>4 besides those reflected here?</p> <p>5 A. I don't know. I'm not part of the AG</p> <p>6 invoicing process.</p> <p>7 Q. As far as you know, all invoices for</p> <p>8 your and AG's work in this case, have they been</p> <p>9 produced?</p> <p>10 A. Yes.</p> <p>11 Q. And I want to ask you a couple of</p> <p>12 questions here. Just look at that first page, for</p> <p>13 instance. Do you see there's a current billing</p> <p>14 section break-out?</p> <p>15 A. Yes.</p> <p>16 Q. It lists AG professional services at</p> <p>17 59,000 and change. Do you see that?</p> <p>18 A. Yes.</p> <p>19 Q. And it lists expert services at \$8,125;</p> <p>20 right?</p> <p>21 A. Yes.</p> <p>22 Q. Is it correct that expert services</p> <p>23 refers to the amounts billed for your time and AG</p> <p>24 professional services reflects the amounts billed</p> <p>25 for all of the other Analysis Group folks who</p>	<p>Page 335</p> <p>1 worked with you on the report?</p> <p>2 A. Yes. That's my understanding.</p> <p>3 Q. And why is Aurobindo Pharma, Ltd.'s</p> <p>4 share, 16.67 percent, broken out here in this</p> <p>5 invoice?</p> <p>6 MR. DORNER: Object to form. This was</p> <p>7 communicated in our document responses. And,</p> <p>8 furthermore, calls for speculation.</p> <p>9 THE WITNESS: I don't know the</p> <p>10 arrangement between the manufacturers, defense</p> <p>11 counsel in terms of payments. All I see is what</p> <p>12 the portion is listed on this invoice.</p> <p>13 BY MR. STANOCH:</p> <p>14 Q. Do you know why no other defendant is</p> <p>15 listed, broken out as Aurobindo is?</p> <p>16 MR. DORNER: Object to form. Again, I'd</p> <p>17 refer counsel to our document responses which</p> <p>18 explain this. Lacks foundation. Calls for</p> <p>19 speculation.</p> <p>20 MR. STANOCH: I'm trying to establish</p> <p>21 foundation, Mr. Dorner, with the witness.</p> <p>22 BY MR. STANOCH:</p> <p>23 Q. Please answer the question.</p> <p>24 A. It would be my expectation that each</p> <p>25 defendant would be invoiced separately based upon</p>	<p>Page 336</p> <p>1 whatever agreed upon share of the expenses were</p> <p>2 made.</p> <p>3 Q. Are there other invoices that break out</p> <p>4 other defendants' percentages out there?</p> <p>5 MR. DORNER: Object to form. This is</p> <p>6 summed up in our document responses, which are</p> <p>7 already available. Calls for speculation.</p> <p>8 THE WITNESS: I don't know. I don't see</p> <p>9 AG's invoices besides the one that have been</p> <p>10 produced and shown to me here.</p> <p>11 BY MR. STANOCH:</p> <p>12 Q. Did you see invoices before they're</p> <p>13 issued by AG to one or more defendants in this</p> <p>14 case?</p> <p>15 A. No.</p> <p>16 Q. Going back to AG professional services</p> <p>17 and expert services, would it be correct then that</p> <p>18 the total amount billed by you and AG reflected in</p> <p>19 this invoice would be the sum of the 59,000 and</p> <p>20 change and 8,125?</p> <p>21 A. Yes. That's my reading of this invoice.</p> <p>22 Q. Stand by. I'm going to mark the next</p> <p>23 exhibit, Exhibit 15.</p> <p>24 (Kosty Exhibit 15 was marked.)</p> <p>25</p>	<p>Page 337</p> <p>1 BY MR. STANOCH:</p> <p>2 Q. Mr. Kosty, can you see this?</p> <p>3 A. Yes.</p> <p>4 Q. And I quickly tried to put this</p> <p>5 together, and there is a typo for December there.</p> <p>6 But we took the amounts for the Analysis Group</p> <p>7 listed in the invoices, the amounts under expert</p> <p>8 services, and we put them here. Do you see that?</p> <p>9 A. Yes.</p> <p>10 Q. Again, so expert services means the</p> <p>11 amounts billed for your time and the amounts</p> <p>12 listed for Analysis Group is for everybody else;</p> <p>13 correct?</p> <p>14 A. Yes.</p> <p>15 Q. So it would be correct, would it not,</p> <p>16 that the total amounts billed for your work on a</p> <p>17 monthly basis then is the sum for each month on</p> <p>18 the invoices; right?</p> <p>19 A. Yes, based on the one we just looked at.</p> <p>20 Q. So the total amount that you and</p> <p>21 Analysis Group combined have billed through your</p> <p>22 work thus far in this case, assuming the numbers</p> <p>23 are transposed accurately from the invoices, is</p> <p>24 \$644,540.45?</p> <p>25 MR. DORNER: Just objection, "assuming</p>
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<p style="text-align: right;">Page 338</p> <p>1 that."</p> <p>2 You can answer.</p> <p>3 THE WITNESS: Yes.</p> <p>4 BY MR. STANOCH:</p> <p>5 Q. Have you done any other work in this</p> <p>6 case that's been invoiced that's not reflected in</p> <p>7 the invoices produced or the chart that's in front</p> <p>8 of you?</p> <p>9 A. No, because February's invoice would not</p> <p>10 go out until march.</p> <p>11 Q. Approximately how much time do you think</p> <p>12 you've billed to this matter for the month of</p> <p>13 February thus far?</p> <p>14 A. I don't know. I'd have to run a report</p> <p>15 off of our time tracking system.</p> <p>16 Q. You don't know how much time you spent</p> <p>17 preparing for today's deposition?</p> <p>18 A. I didn't say that. I said I don't know</p> <p>19 the total hours spent this month on this case.</p> <p>20 Q. About how much time do you think you</p> <p>21 spent in total preparing for today's deposition?</p> <p>22 A. Well, this week I met with counsel and I</p> <p>23 reviewed my own report to go through in</p> <p>24 preparation for today. So probably 16 hours this</p> <p>25 week plus today's time.</p>	<p style="text-align: right;">Page 340</p> <p>1 Hold on. Hold on. We object to the constant back</p> <p>2 and forth from attorney to attorney, particularly</p> <p>3 going back to Mr. Honik when he's already had an</p> <p>4 opportunity to ask his questions. This is</p> <p>5 contrary to the court's directive of how inquiry</p> <p>6 should go. Two attorneys I think is fine, but</p> <p>7 going to back and forth like a tennis match is</p> <p>8 unacceptable. So note our objection to this</p> <p>9 practice.</p> <p>10 MR. HONIK: I have no idea what you're</p> <p>11 talking about. Mr. Goldberg who started the</p> <p>12 examination of Dr. Conti a full day later resumed.</p> <p>13 So your objection is ridiculous.</p> <p>14 BY MR. HONIK:</p> <p>15 Q. Mr. Kosty, there's a few more minutes</p> <p>16 that I need with you to cover one area that we had</p> <p>17 yet to cover. You're familiar with the American</p> <p>18 Society of Health System Pharmacists?</p> <p>19 A. Yes.</p> <p>20 Q. Have you ever been a member of that</p> <p>21 organization?</p> <p>22 A. No. Our consulting practice is more</p> <p>23 ambulatory focused and not hospital.</p> <p>24 Q. Nonetheless, you appreciate that they</p> <p>25 prepare guidelines that are relied upon</p>
<p style="text-align: right;">Page 339</p> <p>1 Q. How much time approximately do you think</p> <p>2 the Analysis Group has spent supporting you to</p> <p>3 this point in February?</p> <p>4 MR. DORNER: Object to form. Calls for</p> <p>5 speculation.</p> <p>6 THE WITNESS: I don't know. I don't</p> <p>7 have access to their time tracking system.</p> <p>8 BY MR. STANOCH:</p> <p>9 Q. How many times have you communicated</p> <p>10 with Analysis Group personnel in connection with</p> <p>11 this litigation in the month of February 2022?</p> <p>12 A. I don't know.</p> <p>13 Q. You don't know?</p> <p>14 A. I don't know, no.</p> <p>15 MR. STANOCH: I'm going to -- for the</p> <p>16 record, I'll correct the December typo and change</p> <p>17 the period ending to January 31, 2021 to 2022 in</p> <p>18 the copy of this, which is part of the record.</p> <p>19 I'll take care of this later.</p> <p>20 I believe I'm going to hand the mic.</p> <p>21 back to Mr. Honik at this point.</p> <p>22 RE-EXAMINATION</p> <p>23 BY MR. HONIK:</p> <p>24 Q. Mr. Kosty, we're in the home stretch.</p> <p>25 MR. DORNER: We object. We object.</p>	<p style="text-align: right;">Page 341</p> <p>1 professionally by P&T committees routinely?</p> <p>2 MR. DORNER: Object to form. Lacks</p> <p>3 foundation. Calls for speculation.</p> <p>4 THE WITNESS: Yeah, they're one of many</p> <p>5 organizations that provide guidelines to P&T</p> <p>6 committees.</p> <p>7 BY MR. STANOCH:</p> <p>8 Q. But my question you to is: Do you</p> <p>9 recognize them and their guidelines as</p> <p>10 authoritative and reliable?</p> <p>11 A. For the hospital market.</p> <p>12 Q. I'm sorry. Only for the hospital</p> <p>13 market?</p> <p>14 A. Right, because an ambulatory entity, a</p> <p>15 Medicare Part D plan is not looking at hospital or</p> <p>16 health system-based formularies or P&T committee</p> <p>17 recommendations.</p> <p>18 Q. Let me unpack that a little bit. Is it</p> <p>19 your testimony that some of their guidelines are</p> <p>20 authoritative and reliable and others are not?</p> <p>21 MR. DORNER: Object to the</p> <p>22 characterization.</p> <p>23 THE WITNESS: You mischaracterized my</p> <p>24 statement. My statement was the P&T committees in</p> <p>25 the ambulatory market, Med D, commercial ASHP</p>

<p style="text-align: right;">Page 342</p> <p>1 guidelines may be reviewed, but is not considered 2 authoritative. It's a guideline, as I mentioned. 3 I mentioned in my report AMCP, the 4 Academy of Managed Care Pharmacy, also has 5 guidelines that are more targeted to the 6 ambulatory market, the managed care market, that 7 have P&T committees that work with prescription 8 drug programs. 9 When I look at ASHP, my process is that 10 they're focused on the hospital market. 11 BY MR. HONIK: 12 Q. And do you know whether or not their 13 guidelines speak to health systems? 14 A. I haven't reviewed those guidelines for 15 this case. 16 Q. You haven't reviewed them? 17 A. Not for this, no. 18 Q. Is that right? 19 MR. HONIK: Can we bring up, Dave, the 20 ASHP guideline that I sent you. 21 MR. STANOCH: Stand by. 22 (Kosty Exhibit 16 was marked.) 23 BY MR. HONIK: 24 Q. Mr. Kosty, let me direct your attention 25 to what we're now going to mark Exhibit 16. As</p>	<p style="text-align: right;">Page 344</p> <p>1 important considerations and recommend processes 2 for formulary system management within the context 3 of a hospital or health system." 4 Did I read that right? 5 A. Yes. 6 Q. A little further down in that paragraph 7 it says, "These guidelines also provide assistance 8 to pharmacists in the organization and operation 9 of the pharmacy and therapeutics (P&T) committee 10 or equivalent body..." 11 Did I read that correct? 12 A. You did. 13 MR. DORNER: Objection. The whole 14 sentence wasn't read. I also object to asking 15 questions about a document -- Mr. Honik, please. 16 I also object to use of a document and asking 17 questions when the witness hadn't had a full 18 opportunity to review -- 19 MR. HONIK: Let me ask you a question. 20 Why do you object to the use of this document? 21 MR. DORNER: I didn't object to the use 22 of this document. I object to the use in asking 23 questions before Mr. Kosty has opportunity to 24 review it in full. He's just testified that he 25 may not have ever seen this before, and he's being</p>
<p style="text-align: right;">Page 343</p> <p>1 you can see, it's an ASHP report, and specifically 2 it's Guidelines on the P&T Committee and the 3 Formulary System. Do you see that? 4 A. Yes. 5 Q. Have you seen this before, or aren't you 6 sure? 7 A. I'm trying to increase the size of it. 8 Q. For the record, this is Volume 78, 9 Number 10, May 15, 2021. Do you see that? 10 MR. DORNER: I think the witness is 11 still trying to get the document on his system in 12 the public folder, Mr. Honik. 13 THE WITNESS: Now it came up. 14 BY MR. STANOCH: 15 Q. The question is: Have you seen this 16 before, or aren't you sure? 17 A. I'm not sure. If I have, I don't recall 18 right offhand. 19 Q. So sitting here today under oath, you're 20 not sure and you don't recall; right? 21 A. That's what I just said, yes. 22 Q. Okay. Do you see where it says Purpose, 23 the purpose of the guideline, lower left? 24 A. Yes. 25 Q. It reads, "These guidelines outline</p>	<p style="text-align: right;">Page 345</p> <p>1 presented with it at the end of a long day. 2 MR. HONIK: Uh-huh. His testimony is he 3 hasn't seen this, right? 4 BY MR. HONIK: 5 Q. Is that your testimony, Mr. Kosty? 6 A. That was not my testimony. 7 MR. DORNER: Objection. Asked and 8 answered. 9 THE WITNESS: I don't recall seeing 10 this. I may have. 11 BY MR. HONIK: 12 Q. Well, you agree that the portion that I 13 read to you quickly, because it is the end of the 14 day, which sets out the purpose of this guideline 15 includes not only hospitals, but health systems; 16 right? 17 A. Yes, within the context of a hospital or 18 health system. 19 Q. Or health system. So it refers to P&T 20 committees or their equivalent bodies; correct? 21 MR. DORNER: Object to the 22 characterization. 23 THE WITNESS: Within a hospital or 24 health system. 25</p>

<p>Page 346</p> <p>1 BY MR. HONIK:</p> <p>2 Q. It's not limited to hospitals, is it?</p> <p>3 A. That's what the context says. The</p> <p>4 purpose of the document, management within the</p> <p>5 context of a hospital or a health system. That's</p> <p>6 what it says.</p> <p>7 Q. Take a look at -- let's go ahead to page</p> <p>8 911 of this document, Exhibit 16. Do you see in</p> <p>9 the third column to the right it says Strategies</p> <p>10 For Managing Medication Use?</p> <p>11 A. Yes.</p> <p>12 Q. And it reads, "Common strategies for</p> <p>13 managing medication use via the formulary include</p> <p>14 use of generic drugs..." and then it lists some</p> <p>15 other items. Do you see that?</p> <p>16 A. Yes.</p> <p>17 Q. Then it says Generic drugs. Do you see</p> <p>18 that section?</p> <p>19 A. I do.</p> <p>20 Q. "Optimizing the number of medication</p> <p>21 entities and products available from the pharmacy</p> <p>22 can produce substantial patient care and financial</p> <p>23 benefits. These benefits are greatly increased</p> <p>24 through the use of generic equivalents (drugs</p> <p>25 considered bioequivalent by FDA [i.e., AB-rated</p>	<p>Page 348</p> <p>1 with generic equivalence ratings, is the name of</p> <p>2 that book like it says in footnote 42. So part of</p> <p>3 that compilation is whether these products are</p> <p>4 considered bioequivalent, i.e., AB-rated products.</p> <p>5 So yes.</p> <p>6 BY MR. HONIK:</p> <p>7 Q. And what it's doing as a guideline is</p> <p>8 encouraging reference to the Orange Books for the</p> <p>9 reasons that we've just gone over in this exhibit;</p> <p>10 correct?</p> <p>11 MR. DORNER: Object to form.</p> <p>12 Characterization. Lacks foundation.</p> <p>13 You can answer.</p> <p>14 THE WITNESS: Yeah, I don't know</p> <p>15 specifically because the Orange Book is produced,</p> <p>16 right. But that data is available in other drug</p> <p>17 compendia sources that includes the therapeutic</p> <p>18 equivalence rating, in this case AB.</p> <p>19 BY MR. HONIK:</p> <p>20 Q. Sir, I'm not sure what you're responding</p> <p>21 to. I'm simply asking you if it isn't true that</p> <p>22 this guideline from a society that you told me is</p> <p>23 reliable speaks to the use of the Orange Book to</p> <p>24 rely upon and receive assurance about the use of</p> <p>25 AB-rated generic drug products.</p>
<p>Page 347</p> <p>1 drug products.])" And there's a footnote number</p> <p>2 42.</p> <p>3 Do you see that, sir?</p> <p>4 A. I do see that.</p> <p>5 Q. And you know that relates to the Orange</p> <p>6 Book; does it not?</p> <p>7 MR. DORNER: Object to form. Lacks</p> <p>8 foundation.</p> <p>9 THE WITNESS: The AB rating does reflect</p> <p>10 the Orange Book, yes.</p> <p>11 BY MR. HONIK:</p> <p>12 Q. Do you have the ability to quickly look</p> <p>13 at footnote 42 to satisfy yourself that they are</p> <p>14 specifically referring to the Orange Book? We can</p> <p>15 look at it on the share screen.</p> <p>16 A. Yes. I see it.</p> <p>17 Q. So you agree that in this ASHP report</p> <p>18 and guideline, they're referring to the positive</p> <p>19 use of the Orange Book for P&T committees; right?</p> <p>20 MR. DORNER: Object to the</p> <p>21 characterization. Lacks foundation.</p> <p>22 You can answer.</p> <p>23 THE WITNESS: I think they're referring</p> <p>24 to the generic equivalent ratings in the Orange</p> <p>25 Book. The Orange Book is the approved products</p>	<p>Page 349</p> <p>1 MR. DORNER: Objection.</p> <p>2 Mischaracterization. Lacks foundation.</p> <p>3 You can answer.</p> <p>4 THE WITNESS: Yeah, this guideline</p> <p>5 refers to the Orange Book, at least in footnote</p> <p>6 42.</p> <p>7 BY MR. HONIK:</p> <p>8 Q. And it encourages P&T committees to</p> <p>9 refer to them to satisfy themselves that the drugs</p> <p>10 are considered bioequivalent by the FDA; correct?</p> <p>11 MR. DORNER: Objection.</p> <p>12 Mischaracterization. Lacks foundation.</p> <p>13 THE WITNESS: I'm just rereading that</p> <p>14 section to see exactly what it says. There's a</p> <p>15 number of reasons why they say you look at the</p> <p>16 Orange Book, yes.</p> <p>17 BY MR. HONIK:</p> <p>18 Q. That's right. There are. And one of</p> <p>19 them is that the drugs by reference to the Orange</p> <p>20 Book are those that are bioequivalent as</p> <p>21 considered by the FDA; correct?</p> <p>22 MR. DORNER: Object to form.</p> <p>23 Characterization.</p> <p>24 THE WITNESS: Yes.</p> <p>25</p>

<p style="text-align: right;">Page 350</p> <p>1 BY MR. HONIK:</p> <p>2 Q. And before we leave the document, it</p> <p>3 encourages, among others, P&T committees to make</p> <p>4 use of that reference; correct?</p> <p>5 MR. DORNER: Object to form.</p> <p>6 Mischaracterization. Lacks foundation.</p> <p>7 BY MR. HONIK:</p> <p>8 Q. That's what it says; right, sir?</p> <p>9 MR. DORNER: Same objections.</p> <p>10 THE WITNESS: Yes.</p> <p>11 BY MR. HONIK:</p> <p>12 Q. I'm sorry. Did you say "yes"?</p> <p>13 A. Yes.</p> <p>14 Q. Thank you. Take a look at your own</p> <p>15 report, sir. Do you have that in front of you?</p> <p>16 A. Yes.</p> <p>17 MR. DORNER: Are you going to direct him</p> <p>18 to a paragraph?</p> <p>19 BY MR. HONIK:</p> <p>20 Q. Take a look at page C-4. That's in your</p> <p>21 Appendix C. This is the beginning of your list of</p> <p>22 books and academic articles that you, yourself,</p> <p>23 relied upon; correct?</p> <p>24 A. Yes.</p> <p>25 Q. Did you say "yes"?</p>	<p style="text-align: right;">Page 352</p> <p>1 Mr. Kosty?</p> <p>2 A. Yes.</p> <p>3 Q. And if you turn to page 8 of her report,</p> <p>4 beginning at paragraph 47, this is where -- we're</p> <p>5 going to call this Exhibit 17, by the way.</p> <p>6 (Kosty Exhibit 17 was marked.)</p> <p>7 BY MR. HONIK:</p> <p>8 Q. She's got paragraph 47, "The 'AB' rating</p> <p>9 in the FDA Orange Book, based as it is on the</p> <p>10 generic drug manufacturer's ANDA, represents a</p> <p>11 manufacturer's warranty to TPPs and P&T committees</p> <p>12 for placement on a prescription drug formulary."</p> <p>13 And then she drops a footnote number 6.</p> <p>14 Do you see that?</p> <p>15 A. Yes.</p> <p>16 Q. Your criticism of her that she provided</p> <p>17 no support for that proposition is incorrect</p> <p>18 because she, herself, cited the very same</p> <p>19 guideline that you placed on your reliance list;</p> <p>20 isn't that right?</p> <p>21 MR. DORNER: Object to form.</p> <p>22 Mischaracterization. Argumentative.</p> <p>23 You can answer.</p> <p>24 THE WITNESS: No. That's not the case.</p> <p>25 My beef with Dr. Panagos is her use of the word</p>
<p style="text-align: right;">Page 351</p> <p>1 A. I did.</p> <p>2 Q. The very first book or academic article</p> <p>3 that you relied upon is Exhibit 16, isn't it?</p> <p>4 A. Yes.</p> <p>5 Q. Does that refresh your memory that you,</p> <p>6 yourself, placed reliance on this guideline?</p> <p>7 A. Yes.</p> <p>8 Q. Thank you. Now, you criticized</p> <p>9 Dr. Panagos for her reference to the Orange Book</p> <p>10 and the use of it by P&T committees, didn't you?</p> <p>11 A. Yes.</p> <p>12 Q. In fact, at paragraph 201 of your</p> <p>13 report, you call her out for providing no support</p> <p>14 for P&T committees' use of the Orange Book; right?</p> <p>15 A. Yes.</p> <p>16 Q. And, in fact, do you have Ms. Panagos'</p> <p>17 report?</p> <p>18 A. Not in front of me, no.</p> <p>19 MR. HONIK: Can we get that up as well,</p> <p>20 Dave.</p> <p>21 MR. STANOCH: Stand by.</p> <p>22 MR. HONIK: Thank you.</p> <p>23 BY MR. HONIK:</p> <p>24 Q. Obviously in order to criticize her, you</p> <p>25 had to read her entire report, didn't you,</p>	<p style="text-align: right;">Page 353</p> <p>1 warranty. Perhaps we can go back to the ASHP</p> <p>2 guidelines to see if the word warranty is there or</p> <p>3 not.</p> <p>4 BY MR. HONIK:</p> <p>5 Q. Sir, you're not a lawyer. I'm sorry.</p> <p>6 Did you finish?</p> <p>7 A. No, I did not finish. I also went to</p> <p>8 the Orange Book itself, Edition 41, and searched</p> <p>9 it for the word warranty. In the 1600-plus pages</p> <p>10 in the Orange Book, the word warranty is not found</p> <p>11 at all. It's not found once.</p> <p>12 So my beef with Dr. Panagos is her use</p> <p>13 of the word warranty, that the FDA Orange Book</p> <p>14 creates a warranty. That is the issue I have with</p> <p>15 her. And the FDA Orange Book doesn't even mention</p> <p>16 a warranty. So I don't know how she says it</p> <p>17 creates a warranty or represents a manufacturer</p> <p>18 warranty.</p> <p>19 Q. Mr. Kosty, do you remember hours ago</p> <p>20 telling me you're not a lawyer?</p> <p>21 A. Yes.</p> <p>22 Q. And you know Ms. Panagos is not a lawyer</p> <p>23 either; correct?</p> <p>24 A. That's my understanding.</p> <p>25 Q. Do you know how she used the term or</p>

<p style="text-align: right;">Page 354</p> <p>1 word warranty in her report?</p> <p>2 MR. DORNER: Object to form. Calls for</p> <p>3 speculation.</p> <p>4 THE WITNESS: I didn't know what her</p> <p>5 intent is, but the word warranty is more than</p> <p>6 it's just listed. It implies a legal obligation.</p> <p>7 And I don't see that in the Orange Book.</p> <p>8 What I do see in the Orange Book is a</p> <p>9 list of all of the approved drug products the FDA</p> <p>10 has done through either an NDA or an ANDA process.</p> <p>11 They also list BLAs and OTC products. So when I</p> <p>12 went to the Orange Book looking for the word</p> <p>13 warranty, I did not find it.</p> <p>14 BY MR. HONIK:</p> <p>15 Q. Did you read Ms. Panagos' testimony?</p> <p>16 A. No.</p> <p>17 Q. So you don't understand how she used the</p> <p>18 word warranty herself, do you?</p> <p>19 A. I did not read her testimony, no.</p> <p>20 Q. Do you know that the word warranty</p> <p>21 outside of the legal context refers to ability to</p> <p>22 rely upon or to receive assurance about?</p> <p>23 MR. DORNER: Object to form. Lacks</p> <p>24 foundation. Characterization. Calls for a legal</p> <p>25 conclusion.</p>	<p style="text-align: right;">Page 356</p> <p>1 A. Yes.</p> <p>2 Q. And don't you agree that if you've got</p> <p>3 an AB-rated drug that purports to be therapeutic</p> <p>4 equivalent, that that imparts certain specific</p> <p>5 criteria that one can rely upon?</p> <p>6 MR. DORNER: Object to form. Calls for</p> <p>7 a legal conclusion. Lacks foundation.</p> <p>8 THE WITNESS: There's requirements in</p> <p>9 the Orange Book under that therapeutic equivalence</p> <p>10 rating that specifies it, yes.</p> <p>11 BY MR. HONIK:</p> <p>12 Q. That's right. And when you look at the</p> <p>13 criteria set out in the Orange Book for that</p> <p>14 therapeutic equivalent, it connotes very specific</p> <p>15 criteria that the reader can rely upon in</p> <p>16 believing a drug which is AB rated; correct?</p> <p>17 MR. DORNER: Same objections as last</p> <p>18 time plus improper characterization.</p> <p>19 THE WITNESS: Yes. It explains the AB</p> <p>20 rating and the components behind it, yes.</p> <p>21 BY MR. HONIK:</p> <p>22 Q. And the reason one reads it and can rely</p> <p>23 upon it is because that criteria comes from the</p> <p>24 FDA; correct?</p> <p>25 MR. DORNER: Objection. Improper</p>
<p style="text-align: right;">Page 355</p> <p>1 THE WITNESS: Yeah, I don't know what</p> <p>2 her testimony was, but the warranty -- where I</p> <p>3 read this and my comments were I just explained.</p> <p>4 BY MR. HONIK:</p> <p>5 Q. Do you know that when somebody warrants</p> <p>6 something outside of the legal definition of</p> <p>7 warrant, that it could mean to rely upon or</p> <p>8 receive assurance about?</p> <p>9 MR. DORNER: Same objections as last</p> <p>10 time, plus asked and answered.</p> <p>11 THE WITNESS: Yeah, I think in a</p> <p>12 consumer perspective, when I look at a warranty,</p> <p>13 when I buy something, the manufacturer provides a</p> <p>14 warranty and it includes certain components that I</p> <p>15 as a consumer can expect.</p> <p>16 So it's a document that's given to me</p> <p>17 when I purchase, say, a technology item that</p> <p>18 indicates the warranty the manufacturer is</p> <p>19 standing behind. That is how I viewed her</p> <p>20 testimony in this report. And that's why I made</p> <p>21 the objection I did in my report.</p> <p>22 BY MR. HONIK:</p> <p>23 Q. Sir, did you actually look at the Orange</p> <p>24 Book and determine how they use the term</p> <p>25 therapeutic equivalent?</p>	<p style="text-align: right;">Page 357</p> <p>1 characterization. Lacks foundation. Calls for a</p> <p>2 legal conclusion. Mischaracterizes.</p> <p>3 You can answer.</p> <p>4 THE WITNESS: Yes. It's a compilation</p> <p>5 of in this case an ANDA approval process by the</p> <p>6 manufacturer.</p> <p>7 MR. HONIK: Dave, can we bring up the</p> <p>8 Orange Book Preface section that we have</p> <p>9 available.</p> <p>10 MR. STANOCH: Exhibit 18.</p> <p>11 (Kosty Exhibit 18 was marked.)</p> <p>12 BY MR. HONIK:</p> <p>13 Q. We have, Mr. Kosty, on page 1 here the</p> <p>14 Orange Book, Food and Drug Administration Center</p> <p>15 for Drug Evaluation and Research, Approved Drug</p> <p>16 Products for Therapeutic Equivalence Evaluations.</p> <p>17 Do you see that?</p> <p>18 A. Yes.</p> <p>19 Q. You're familiar with this preface to the</p> <p>20 42nd Edition?</p> <p>21 A. I'm familiar with the contents but not</p> <p>22 every specific item in here. But, yes, generally</p> <p>23 so.</p> <p>24 Q. You're certainly aware that Ms. Panagos</p> <p>25 was referring to this document; correct?</p>

<p style="text-align: right;">Page 358</p> <p>1 A. Yes.</p> <p>2 Q. It says, "The publication, Approved Drug</p> <p>3 Products for Therapeutic Equivalence Evaluations,</p> <p>4 (the List, commonly known as the Orange Book)</p> <p>5 identifies drug products approved on the basis of</p> <p>6 safety and effectiveness by the FDA under the</p> <p>7 Federal Food, Drug, and Cosmetic Act."</p> <p>8 Did I read that correctly?</p> <p>9 A. You did.</p> <p>10 Q. You know that those who use the Orange</p> <p>11 Book rely upon it; correct?</p> <p>12 MR. DORNER: Object to form. Vague.</p> <p>13 Lacks foundation. Mischaracterizes.</p> <p>14 THE WITNESS: When you say rely upon it,</p> <p>15 in what context?</p> <p>16 BY MR. HONIK:</p> <p>17 Q. In the following context.</p> <p>18 MR. HONIK: Turn to the page, Dave, that</p> <p>19 says Therapeutic Equivalence.</p> <p>20 BY MR. HONIK:</p> <p>21 Q. As Exhibit 16 suggested, P&T committees</p> <p>22 are encouraged within the guidelines to rely upon</p> <p>23 this for determining when a drug is</p> <p>24 therapeutically equivalent among other things;</p> <p>25 correct?</p>	<p style="text-align: right;">Page 360</p> <p>1 MR. DORNER: Objection. Outside the</p> <p>2 scope.</p> <p>3 BY MR. HONIK:</p> <p>4 Q. And you're familiar with the criteria</p> <p>5 that are enumerated here, aren't you, Mr. Kosty?</p> <p>6 MR. DORNER: Same objection.</p> <p>7 THE WITNESS: Yes.</p> <p>8 BY MR. HONIK:</p> <p>9 Q. And you know from your own experience as</p> <p>10 well as the guideline we looked at in Exhibit 16</p> <p>11 that P&T committees are encouraged to rely upon</p> <p>12 this criteria; correct?</p> <p>13 MR. DORNER: Object to form. Improper</p> <p>14 characterization of both the document and the</p> <p>15 testimony. Lacks foundation. Outside the scope.</p> <p>16 Speculative.</p> <p>17 You can answer.</p> <p>18 THE WITNESS: Yes, based on that ASHP</p> <p>19 guideline.</p> <p>20 BY MR. HONIK:</p> <p>21 Q. And that's exactly what Ms. Panagos</p> <p>22 relied upon in support of her statement that you</p> <p>23 criticized; correct?</p> <p>24 MR. DORNER: Object to form.</p> <p>25 Speculation. Characterization.</p>
<p style="text-align: right;">Page 359</p> <p>1 MR. DORNER: Object to form. Improper</p> <p>2 characterization. Misstates the testimony. Lacks</p> <p>3 foundation.</p> <p>4 You can answer.</p> <p>5 THE WITNESS: Yes.</p> <p>6 BY MR. HONIK:</p> <p>7 Q. Correct?</p> <p>8 A. Yes.</p> <p>9 Q. And it says, "Approved drug products are</p> <p>10 considered to be therapeutic equivalents if they</p> <p>11 are pharmaceutical equivalents for which</p> <p>12 bioequivalence has been demonstrated, and they can</p> <p>13 be expected to have the same clinical effect and</p> <p>14 safety profile when administered to patients under</p> <p>15 the conditions specified in the labeling."</p> <p>16 Did I read that correctly?</p> <p>17 A. Yes.</p> <p>18 MR. DORNER: And I'll object to outside</p> <p>19 the scope at this point.</p> <p>20 BY MR. HONIK:</p> <p>21 Q. It then says, "FDA classifies as</p> <p>22 therapeutically equivalent those drug products</p> <p>23 that meet the following general criteria."</p> <p>24 Do you see that?</p> <p>25 A. Yes.</p>	<p style="text-align: right;">Page 361</p> <p>1 THE WITNESS: Yeah, back to her use of</p> <p>2 the word warranty, that's what my objection was,</p> <p>3 and I previously stated why.</p> <p>4 BY MR. HONIK:</p> <p>5 Q. Well, if we understand her to use</p> <p>6 warranty as ability to rely upon or receive</p> <p>7 assurance about, you would agree with that</p> <p>8 statement; right?</p> <p>9 MR. DORNER: Object to form. Improper</p> <p>10 characterization. Calls for speculation. Lacks</p> <p>11 foundation.</p> <p>12 You can answer.</p> <p>13 THE WITNESS: Yes. If she had written</p> <p>14 that in her report, it would have been clear what</p> <p>15 she was getting to. She did not write that in the</p> <p>16 report.</p> <p>17 BY MR. HONIK:</p> <p>18 Q. Can you read to us what the fifth</p> <p>19 criteria is for the FDA classifying as</p> <p>20 therapeutically equivalent drugs that meet the</p> <p>21 criteria?</p> <p>22 MR. DORNER: Object to form. Outside</p> <p>23 the scope.</p> <p>24 THE WITNESS: What page are you on?</p> <p>25</p>

<p>Page 362</p> <p>1 BY MR. HONIK:</p> <p>2 Q. It's the one we're looking at presently.</p> <p>3 "FDA classifies as therapeutically equivalent</p> <p>4 those drug products that meet the following</p> <p>5 general criteria." And I've asked you to read</p> <p>6 into the record and for our benefit what the fifth</p> <p>7 criteria is.</p> <p>8 MR. DORNER: Object to form. Outside</p> <p>9 the scope.</p> <p>10 THE WITNESS: I'm not seeing it on the</p> <p>11 screen. That's my issue. I'm trying to ask you</p> <p>12 what page is this on in the document that I can go</p> <p>13 to in a different --</p> <p>14 BY MR. HONIK:</p> <p>15 Q. Mr. Stanoch just highlighted it for you</p> <p>16 on the screen share. You can read it that way.</p> <p>17 A. Can you make that bigger, please?</p> <p>18 Number five -- sorry to squint into the camera.</p> <p>19 "They are manufactured" --</p> <p>20 MR. DORNER: This is the wrong exhibit.</p> <p>21 THE WITNESS: "They are manufactured in</p> <p>22 compliance with current good manufacturing</p> <p>23 practice regulations."</p> <p>24 BY MR. HONIK:</p> <p>25 Q. So you acknowledge that that is one of</p>	<p>Page 363</p> <p>1 the FDA's criteria for achieving therapeutic</p> <p>2 equivalence; right?</p> <p>3 MR. DORNER: Objection. Misstates the</p> <p>4 testimony. Argumentative. Outside the scope of</p> <p>5 the report.</p> <p>6 THE WITNESS: Yes. That's what it reads</p> <p>7 here.</p> <p>8 BY MR. HONIK:</p> <p>9 Q. And you were aware of that when you</p> <p>10 authored your report; correct?</p> <p>11 MR. DORNER: Same objections.</p> <p>12 THE WITNESS: Yes.</p> <p>13 BY MR. HONIK:</p> <p>14 Q. And you're aware that Ms. Panagos relied</p> <p>15 upon the Orange Book for that reason among others;</p> <p>16 correct?</p> <p>17 MR. DORNER: Object to form.</p> <p>18 Speculation. Lacks foundation.</p> <p>19 THE WITNESS: Yeah, I don't know what</p> <p>20 she relied on in her report.</p> <p>21 BY MR. HONIK:</p> <p>22 Q. Well, you relied upon Exhibit 16, which</p> <p>23 is the guideline that makes reference to this; did</p> <p>24 you not?</p> <p>25 A. Yes.</p>	<p>Page 364</p> <p>1 Q. Did you cite that as a reliance material</p> <p>2 for some other reason or purpose, Mr. Kosty?</p> <p>3 A. No.</p> <p>4 Q. And you don't disagree that this</p> <p>5 criteria is FDA generated for therapeutic</p> <p>6 equivalence; right?</p> <p>7 MR. DORNER: Object to form. Outside</p> <p>8 the scope.</p> <p>9 Once again, you can answer.</p> <p>10 THE WITNESS: I don't disagree. That's</p> <p>11 what the FDA has as the regulation.</p> <p>12 BY MR. HONIK:</p> <p>13 Q. Mr. Kosty, those are all the questions</p> <p>14 that we have of you today. For our purposes, and</p> <p>15 certainly the defense may ask you questions</p> <p>16 presently, but for our purposes, we intend to keep</p> <p>17 this deposition open. And I will instruct you and</p> <p>18 counsel to retain and do nothing to disrupt or</p> <p>19 destroy any of your electronically or paper saved</p> <p>20 material regarding your contact with AG.</p> <p>21 Do you understand that instruction?</p> <p>22 A. Yes.</p> <p>23 MR. DORNER: We object. Sorry. Go</p> <p>24 ahead.</p> <p>25</p>	<p>Page 365</p> <p>1 BY MR. HONIK:</p> <p>2 Q. And any other materials that you may</p> <p>3 have that we asked for in our Notice of Deposition</p> <p>4 about which objections were raised.</p> <p>5 MR. HONIK: With that, I yield the</p> <p>6 floor. Anybody have questions of Mr. Kosty?</p> <p>7 MR. DORNER: Well, first of all, we</p> <p>8 object to keeping the deposition open, absolutely</p> <p>9 and completely. Second of all, we've set forth</p> <p>10 all the objections to any requests that you've</p> <p>11 made, and you can reference those and find the</p> <p>12 defense's position on that.</p> <p>13 There's no basis for this deposition to</p> <p>14 be kept open whatsoever. With that said, we can</p> <p>15 go off the record. We may have more to say off</p> <p>16 the record, but we'd like to take -- let's go to</p> <p>17 6:35 just to confer among us as to whether or not</p> <p>18 there are any further questions for Mr. Kosty.</p> <p>19 THE VIDEOGRAPHER: Off the record 6:21.</p> <p>20 (Recess from 6:21 p.m. to 6:36 p.m.)</p> <p>21 THE VIDEOGRAPHER: We are back on the</p> <p>22 record at 6:36.</p> <p>23 EXAMINATION</p> <p>24 BY MS. ANDRAS:</p> <p>25 Q. Hi, Mr. Kosty. As you know, I'm Tiffany</p>
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1 Andras, and I represent Teva Pharmaceuticals in
2 this case.
3 MR. HONIK: Tiffany, I can barely hear
4 you. Can you speak up?
5 MS. ANDRAS: Can we go off the record
6 for a second.
7 THE VIDEOGRAPHER: Off the record at
8 6:36.
9 (There was a pause in the proceedings.)
10 THE VIDEOGRAPHER: We are back on the
11 record at 6:36.
12 BY MS. ANDRAS:
13 Q. Mr. Kosty, earlier today Mr. Stanoch
14 asked some questions about the two examples of
15 business consolidations that you cite to in your
16 report in paragraphs 153 and 154.
17 Do you recall that?
18 A. Yes.
19 Q. Do you have experience working with
20 entities attempting to integrate and combine
21 disparate sets of claims data?
22 A. Yes, I do.
23 Q. Approximately how many times have you
24 been involved with projects with that task?
25 A. A dozen times or so.

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1 Q. And did those projects involve a
2 combination of two or more entities?
3 A. Yes.
4 Q. How many times did it involve a
5 combination with two entities?
6 A. Probably 95 percent of the time.
7 Q. Did you rely on those experiences to
8 inform your opinions in this case?
9 A. I did, yes.
10 Q. And how many of the projects that you
11 worked on that involved attempting to integrate
12 and combine disparate assets of claims data were
13 there data discrepancies that were discovered
14 during the testing and validation process?
15 A. Every time.
16 Q. Mr. Kosty, do you recall Mr. Honik
17 asking some hypothetical questions about the
18 supply curve?
19 A. Yes.
20 Q. Did consumers and TPPs actually purchase
21 the at-issue VCDs during the time period before
22 the recalls in this case?
23 A. Yes.
24 MR. HONIK: I'm sorry. I didn't catch
25 the question. Can I have it read back by Ann.

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1 (The following record was read back:
2 "Q Did consumers and TPPs actually
3 purchase the at-issue VCDs during the time
4 period before the recalls in this case?")
5 THE WITNESS: Yes.
6 BY MS. ANDRAS:
7 Q. So there was, in fact, a supply
8 available for purchases at the time those
9 purchases were made?
10 A. Yes.
11 Q. Was there, in fact, a supply curve?
12 A. Yes. They had the ability to buy
13 products that was supplied, yes.
14 Q. And was there a price?
15 A. Yes.
16 MS. ANDRAS: Nothing further.
17 MR. HONIK: Any other questions?
18 MS. ANDRAS: Nope.
19 RE-EXAMINATION (Continued)
20 BY MR. HONIK:
21 Q. Mr. Kosty, do you know what the
22 definition from an economics standpoint of a
23 supply curve is?
24 A. Yes.
25 Q. What is that?

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1 A. It's a supply of products for purchase
2 in the marketplace.
3 Q. Do you have any other definition or
4 understanding of it?
5 A. That's my definition of it, yes.
6 Q. Do you understand, have any
7 understanding that Dr. Conti used it and qualified
8 it with the word legitimate? Do you remember
9 that?
10 A. I do remember that, and that was the
11 first time I've ever seen that word as an
12 adjective for a supply curve.
13 Q. And is that right, you've never read or
14 heard in any academic publication or otherwise the
15 term legitimate supply curve?
16 MS. ANDRAS: Objection. Form.
17 Foundation.
18 THE WITNESS: I don't read academic
19 economic theory publications. That's not on my
20 reading list, no.
21 BY MR. HONIK:
22 Q. I gather that you don't. You do concede
23 that there has to be a meeting of the supply curve
24 or the demand curve for there to be an associated
25 price; correct?

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<p>1 A. Yes. That happened in this case when 2 there was a supply of VCD products that was 3 purchased by wholesalers and retailers at a price 4 in the marketplace, yes. 5 Q. And what you're trying to convey is that 6 there was an actual supply of illegitimate 7 product; correct? 8 MS. ANDRAS: Objection. 9 Mischaracterizes prior testimony. Form. 10 THE WITNESS: I didn't say that. That 11 does mischaracterize it. I said there was a 12 supply of that product available for purchase in 13 the marketplace. 14 BY MR. HONIK: 15 Q. Sir, you don't argue that there was 16 contaminated VCDs in the marketplace during the 17 relevant class period; correct? 18 MS. ANDRAS: Objection. Form. 19 THE WITNESS: I've never used the word 20 contaminated. There were impurities identified in 21 those products, yes. 22 BY MR. HONIK: 23 Q. And you don't disagree that we 24 established today extensively with your help that 25 according to the FDA, it's a prohibited act to</p>	<p>1 yet you authored a nearly hundred page, more than 2 a hundred-page report criticizing Dr. Conti for 3 her methodology, didn't you? 4 A. The whole hundred pages didn't 5 criticize, but the total report was a hundred 6 pages, yes. 7 Q. Sir, the thrust of your criticism of 8 Dr. Conti is that she used an improper 9 methodology; right? 10 MS. ANDRAS: Ruben, I'm going to object. 11 This is outside the scope of my redirect. I don't 12 believe I even discussed Dr. Conti's methodology. 13 And you're just trying to rehash ground that you 14 already covered on direct. 15 MR. HONIK: Your objection is noted. 16 BY MR. HONIK: 17 Q. Can you answer my question, Mr. Kosty? 18 A. Could you repeat it please or read it 19 back? 20 Q. You criticized Dr. Conti extensively for 21 her methodology, that is, for I think you 22 described it as a fanciful world that doesn't 23 exist in the real world; isn't that right? 24 A. That's correct. 25 Q. And what you meant by that is that her</p>
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<p>1 place into the stream of commerce a contaminated 2 or adulterated drug; correct? 3 MS. ANDRAS: Objection. Form. 4 Foundation. Misstate prior testimony. Calls for 5 a legal conclusion. And outside the scope. 6 THE WITNESS: My point was the product 7 was available for purchase and it was purchased. 8 BY MR. HONIK: 9 Q. Sir, of course, it was purchased. You 10 understand the entire reason for this lawsuit is 11 the allegation that it was improperly in the 12 marketplace and those that purchased it should 13 have their money back. Do you understand that? 14 A. Yes. 15 Q. And that what Dr. Conti did from an 16 econometric standpoint is to model what that would 17 look like if the manufacturers did not break the 18 law? 19 MS. ANDRAS: Objection. Argumentative. 20 Assumes facts not in evidence. Calls for 21 speculation. And outside the scope. 22 THE WITNESS: It's outside my scope, and 23 it calls for a legal conclusion. 24 BY MR. HONIK: 25 Q. Sir, you say it's outside the scope, and</p>	<p>1 methodology was wrong. She considered the wrong 2 universe in arriving at a damage calculation; 3 correct? 4 MS. ANDRAS: Objection. Form. 5 Foundation. Outside the scope of my redirect. 6 Outside the scope of his opinion. And 7 mischaracterizes testimony. 8 THE WITNESS: Yeah, mischaracterizes my 9 testimony. My testimony was Dr. Conti's model, 10 she creates this assumption that's infallible. 11 And I'm saying in the real world in the 12 pharmaceutical industry, these products were 13 available for purchase. They were purchased and 14 dispensed to patients. And once the impurities 15 were identified, they were taken off the market in 16 voluntarily recalls with the manufacturers. 17 That's what my problem is. It just 18 dismisses any of the things that actually happened 19 in the marketplace. When I say I'm an industry 20 expert, those are the industry things that had to 21 be dealt with because those products were 22 purchased. They were consumed. So we had to deal 23 with how it works in the real world. That's my 24 beef with her methodology. 25 She just assumes all that never happened</p>

<p>Page 374</p> <p>1 when, in fact, it did. I'm saying in the real 2 world, those things happened and they had to be 3 addressed. 4 BY MR. HONIK: 5 Q. Sir, it's been a long day, but you 6 understand that the metric or criteria for damage 7 assessment is going to be determined as a legal 8 matter? Do you accept that? 9 MS. ANDRAS: Ruben, this way outside the 10 scope of my direct examination now. If you don't 11 cut it out, we're going to pull the witness. This 12 is getting well outside the scope. I asked him 13 simple questions about the supply curve. I did 14 not mention Dr. Conti's name. And now you're 15 talking about measure of damages again. And we 16 did not ask him questions about that. 17 MR. HONIK: Your objection is noted. 18 MS. ANDRAS: We're going to pull the 19 witness, Ruben, if you continue this. You had 20 your chance for questions. 21 MR. HONIK: Your objection is noted. 22 BY MR. HONIK: 23 Q. Mr. Kosty, can you answer my question? 24 A. I testified earlier that's a legal 25 decision that I'm not qualified to make.</p> <p>Page 375</p> <p>1 Q. That's correct. And if a legal decision 2 is made that assumes, as Dr. Conti did, that the 3 drugs were under the FDA definition adulterated 4 and, therefore, should not have been in the 5 marketplace, you agree the measure of damages is 6 the purchase price; correct? 7 MS. ANDRAS: Objection. Outside the 8 scope of redirect. Outside the scope of his 9 opinion. Form. And calls for a legal conclusion. 10 BY MR. HONIK: 11 Q. Isn't that right? 12 A. I don't know. Like I said earlier, I'm 13 not a legal person to make those legal decisions. 14 That's up to the court. 15 Q. Sir, I asked you earlier today if you 16 are to assume that the benefit of the bargain was 17 not achieved here -- I showed you any number of 18 cases including language from the judge in charge 19 of this case -- you would agree that the measure 20 of damages, and I know you don't agree with it, 21 but under those circumstances, the measure of 22 damages is the actual price spent or purchased for 23 these drugs; correct? 24 MS. ANDRAS: Form. Objection. Form. 25 Foundation. Mischaracterizes prior testimony.</p>	<p>Page 376</p> <p>1 And requires a legal conclusion. And outside the 2 scope of both redirect and his opinion. And asked 3 and answered. 4 BY MR. HONIK: 5 Q. Right, Mr. Kosty? 6 A. In your narrowly defined hypothetical, I 7 would think that would be the case. 8 Q. Thank you. I appreciate that. 9 MR. HONIK: With that I have no further 10 questions. Are we done? 11 MS. ANDRAS: Done. 12 MR. HONIK: Subject to the statement I 13 placed on the record a little while ago and 14 certainly your objection, Drew, I think we're done 15 for the night. 16 MR. DORNER: We will read and sign. And 17 certainly to our objection, this is not going to 18 be kept open. 19 MR. HONIK: Thank you, Mr. Kosty. Thank 20 you, Ann, and Mr. Video. 21 THE VIDEOGRAPHER: Off the record at 22 6:46. 23 (Whereupon, at 6:46 p.m. the taking of 24 the instant deposition ceased.) 25</p> <p>Page 377</p> <p>1 COMMONWEALTH OF PENNSYLVANIA) 2 COUNTY OF ALLEGHENY) SS: 3 C E R T I F I C A T E 4 I, Ann Medis, RPR, CLR, CSR-WA and 5 Notary Public within and for the Commonwealth of 6 Pennsylvania, do hereby certify: 7 That TIMOTHY E. KOSTY, the witness whose 8 deposition is hereinbefore set forth, was duly 9 sworn by me and that such deposition is a true 10 record of the testimony given by such witness. 11 I further certify the inspection, 12 reading and signing of said deposition were not 13 waived by counsel for the respective parties and 14 by the witness. 15 I further certify that I am not related 16 to any of the parties to this action by blood or 17 marriage and that I am in no way interested in the 18 outcome of this matter. 19 IN WITNESS WHEREOF, I have hereunto set 20 my hand this 28th day of February, 2022. 21 22 23 _____ 24 Notary Public 25</p>
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1 COMMONWEALTH OF PENNSYLVANIA) E R R A T A
2 COUNTY OF ALLEGHENY) S H E E T

3

4 I, TIMOTHY E. KOSTY, have read the foregoing pages
5 of my deposition given on February 24, 2022, and
6 wish to make the following, if any, amendments,
7 additions, deletions or corrections:

8

9 Page Line Change and reason for change:

10

11 _____

12

13 _____

14

15 _____

16

17 _____

18

19 _____

20

21 _____

22

23 In all other respects, the transcript is true and

24 correct.

25

26 _____

27

28 TIMOTHY E. KOSTY

29

30 _____ day of _____, 2022.

31

32 _____

33

34 Notary Public

35

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Exhibit 211

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF NEW JERSEY
3 *****
4 IN RE: VALSARTAN, LOSARTAN,
5 AND IRBESARTAN PRODUCTS MDL No. 2875
6 LIABILITY LITIGATION
7 *****
8 THIS DOCUMENT APPLIES TO ALL HON ROBERT B.
9 CASES KUGLER
10 *****
11 MARCH 25, 2022
12 CONFIDENTIAL INFORMATION - SUBJECT TO
13 PROTECTIVE ORDER
14 Videotaped Deposition of LAUREN J. STIROH,
15 Ph.D., commencing at 10:13 a.m., at the offices of
16 Duane Morris, LLP, 1540 Broadway, New York, New
17 York, before Jeffrey Benz, a Certified Realtime
18 Reporter, Registered Merit Reporter and Notary
19 Public within and for the State of New York.
20
21
22
23
24

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<p>1 THE VIDEOGRAPHER: We are now on the</p> <p>2 record. My name is Danny Ortega, and I am</p> <p>3 the legal videographer for Golkow</p> <p>4 Litigation Services.</p> <p>5 Today's date is March 25, 2022, and</p> <p>6 the time is 10:13 a.m.</p> <p>7 This video deposition is being held at</p> <p>8 1540 Broadway, New York, New York, in the</p> <p>9 matter of Valsartan, Losartan, and</p> <p>10 Irbesartan Products Liability Litigation,</p> <p>11 for the United States District Court,</p> <p>12 District of New Jersey.</p> <p>13 The deponent today is Dr. Lauren</p> <p>14 Stiroh.</p> <p>15 All counsel will be noted on the</p> <p>16 stenographic record.</p> <p>17 The court reporter today is Jeff Benz,</p> <p>18 who will now swear in the witness.</p> <p>19 LAUREN J. STIROH, Ph.D.,</p> <p>20 called as a witness, having been first</p> <p>21 duly sworn by Jeffrey Benz, a Notary</p> <p>22 Public within and for the State of New</p> <p>23 York, was examined and testified as</p> <p>24 follows:</p>	<p>1 many depositions before. I don't know how many</p> <p>2 you've done remotely since the pandemic. But</p> <p>3 there are a couple of housekeeping items that I</p> <p>4 think are worth mentioning so that we can end up</p> <p>5 with a good transcription and video of your</p> <p>6 testimony today.</p> <p>7 First, I'll be the principal</p> <p>8 questioner today on the plaintiffs' side, and as</p> <p>9 is always the case, it's my job to make myself</p> <p>10 clearly understood to you.</p> <p>11 If you don't understand a question or</p> <p>12 you haven't heard my question, if there's a</p> <p>13 technical problem, it's really important that</p> <p>14 you let me know so that I have an opportunity to</p> <p>15 restate it or clarify it for your benefit.</p> <p>16 Can we agree to that?</p> <p>17 A. Yes.</p> <p>18 Q. I'm sure you're aware that it's</p> <p>19 important that we not speak over one another,</p> <p>20 largely because the court reporter needs to be</p> <p>21 able to take down one speaker at a time.</p> <p>22 That's sometimes a challenge when it's</p> <p>23 conducted remote. I'll do my level best not to</p> <p>24 ask a new question as you're speaking, and if</p>
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<p>1 EXAMINATION BY MR. HONIK:</p> <p>2 Q. Dr. Stiroh, good morning to you once</p> <p>3 again.</p> <p>4 A. Good morning.</p> <p>5 Q. As I introduced myself briefly to you</p> <p>6 earlier, my name is Ruben Honik. I am one of</p> <p>7 the plaintiffs' attorneys in this case. There</p> <p>8 are, as you might expect, a number of other</p> <p>9 plaintiffs' lawyers who are observing on Zoom,</p> <p>10 together with a great many defense attorneys.</p> <p>11 You're aware of all that?</p> <p>12 A. I am, yes.</p> <p>13 Q. And I know that you've given testimony</p> <p>14 under oath before, and I want to take a moment,</p> <p>15 in a moment, to highlight a couple things.</p> <p>16 But inasmuch as I'm in Philadelphia</p> <p>17 and you're in New York, who is in the room with</p> <p>18 you?</p> <p>19 A. The court reporter, the videography,</p> <p>20 and Seth Goldberg.</p> <p>21 Q. Okay. And I gather you're in the</p> <p>22 offices of Duane Morris in New York?</p> <p>23 A. I am.</p> <p>24 Q. I don't know -- I know you've given</p>	<p>1 you could, after you give your answer, maybe</p> <p>2 pause for a second in the event that</p> <p>3 Mr. Goldberg or one of the other defense lawyers</p> <p>4 needs to make an objection, that could be noted</p> <p>5 as well.</p> <p>6 Can you do that for me?</p> <p>7 A. Yes.</p> <p>8 Q. I'm going to be marking some exhibits,</p> <p>9 most if not all of which I hope are in paper</p> <p>10 form near you.</p> <p>11 Do you have, for example, your report</p> <p>12 with you?</p> <p>13 A. I do.</p> <p>14 Q. Well, for the benefit of the record,</p> <p>15 when the opportunity arises, we're going to mark</p> <p>16 that as Exhibit 1, Stiroh 1.</p> <p>17 (Expert report of Lauren J. Stiroh,</p> <p>18 Ph.D. was marked Stiroh Exhibit 1 for</p> <p>19 identification, as of this date.)</p> <p>20 Q. Is the copy that you have, does it</p> <p>21 contain the list of your reliance materials?</p> <p>22 A. It does.</p> <p>23 Q. And does it contain your CV as well?</p> <p>24 A. It does.</p>

<p>Page 10</p> <p>1 Q. And you're satisfied that the copy 2 that we're going to mark Exhibit 1 is your true 3 and correct report that you issued, or is dated 4 January 12th of this year?</p> <p>5 A. Let me just flip through it briefly.</p> <p>6 THE WITNESS: I think that's going to 7 be Conti.</p> <p>8 Can you pass me? 9 (Witness reviewing document.)</p> <p>10 A. It is.</p> <p>11 Q. Dr. Stiroh, I assume you've had an 12 opportunity to review your report or 13 refamiliarize yourself with it before today?</p> <p>14 A. Yes.</p> <p>15 Q. You've, doubtless, had time to prepare 16 with defense counsel who engaged you as well?</p> <p>17 A. I have.</p> <p>18 Q. And you feel ready this morning to 19 discuss the opinions that you express in that 20 report, to me?</p> <p>21 A. I do.</p> <p>22 Q. And in paragraph 5 of your report, 23 Exhibit 1, you describe your assignment. If you 24 could turn to that section.</p> <p>Page 11</p> <p>1 A. I have it in front of me.</p> <p>2 Q. And -- thank you.</p> <p>3 And specifically, as I read it, you 4 [indistinct], as well as the things that you did 5 not do; right?</p> <p>6 A. I'm sorry. I lost a little bit of 7 that question. If you don't mind saying it 8 again.</p> <p>9 Q. Not at all.</p> <p>10 As I read that paragraph entitled 11 Assignment, what I take it you did was to 12 enumerate the things --</p> <p>13 MR. GOLDBERG: Hang on a second, 14 Ruben.</p> <p>15 Q. -- that you didn't do; right?</p> <p>16 MR. GOLDBERG: Ruben, hang on one 17 second. We're getting a little bit of a 18 delay.</p> <p>19 MR. HONIK: Yes. I'm experiencing a 20 little bit of it here, but it's mostly the 21 image that Dr. Stiroh is a little bit 22 halting.</p> <p>23 Can we have the videographer address 24 that?</p>	<p>Page 12</p> <p>1 MR. GOLDBERG: Let's see if it goes 2 away, because it's a little bit -- 3 you're -- you're also sort of coming in and 4 out a little bit.</p> <p>5 So why don't you go ahead and let's 6 see if it goes away.</p> <p>7 MR. HONIK: Seth, I must tell you, 8 you're very crisp, but Dr. Stiroh is a 9 little fuzzy, and there's a bit of a delay.</p> <p>10 I guess all we can do is just go 11 forward and see how it goes. Okay?</p> <p>12 MR. GOLDBERG: Yeah.</p> <p>13 Q. So let me reload the question, 14 Dr. Stiroh.</p> <p>15 We're looking -- excuse me -- at your 16 paragraph 5 together, which you've headed, 17 Assignment.</p> <p>18 And I'm simply trying to establish if 19 it isn't so, that in that paragraph, you 20 describe the things -- pardon me -- that you did 21 in discharging the assignment, as well as the 22 things you did not do.</p> <p>23 Is that fair?</p> <p>24 MR. GOLDBERG: Objection to form.</p> <p>Page 13</p> <p>1 A. Generally, yes. Paragraph 5 of my 2 report describes the assignment, and then also 3 certain assumptions or areas of testimony where 4 I am not offering opinion.</p> <p>5 Q. And that's clear to me.</p> <p>6 If you turn to page 2 of your report, 7 we're still in paragraph 5, and if you were to 8 count down about six lines, do you see the 9 sentence that begins, I do not make an 10 assessment?</p> <p>11 A. I see that.</p> <p>12 Q. From that line forward, you enumerate 13 certain things that you did not do or assess; 14 correct?</p> <p>15 A. I'm not sure what you mean by I 16 enumerate them.</p> <p>17 I have a sentence that says, I do not 18 make an assessment regarding actual risk of 19 safety issues.</p> <p>20 And I have a sentence towards the end 21 that says, I also do not opine on the legal 22 issues, and goes on.</p> <p>23 Those are two areas where I am 24 clarifying that that is not an area for my</p>
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<p style="text-align: right;">Page 14</p> <p>1 testimony.</p> <p>2 Q. That's right. And all I was really</p> <p>3 getting at is you attempt to list some things</p> <p>4 that you didn't do; correct?</p> <p>5 A. Yes.</p> <p>6 Q. I want to spend some time unpacking</p> <p>7 the language here so I understand the things</p> <p>8 that you didn't do before we talk about some of</p> <p>9 the things that you did do. Okay?</p> <p>10 A. Yes.</p> <p>11 Q. So the first sentence on page 2,</p> <p>12 within paragraph 5 that I would like to direct</p> <p>13 your attention to is the one that begins, I do</p> <p>14 not make an assessment regarding any actual risk</p> <p>15 of safety issues with regard to the subject</p> <p>16 VCDs.</p> <p>17 Do you see that clause?</p> <p>18 A. I do.</p> <p>19 Q. Can you tell me what that means?</p> <p>20 A. Yes. I am not a medical expert and I</p> <p>21 am not intending to offer opinions related to</p> <p>22 the safety risk, if any, of the products at</p> <p>23 issue on the patients who consumed them.</p> <p>24 Q. And in that regard, the sentence</p>	<p style="text-align: right;">Page 16</p> <p>1 or opinions.</p> <p>2 I take into account the possibility</p> <p>3 that the products were -- that the -- the</p> <p>4 impurities were included in the products at</p> <p>5 issue and have an understanding from materials</p> <p>6 that I have read in this case of the impact of</p> <p>7 that, but I am not offering testimony that the</p> <p>8 product -- the impurities were included in the</p> <p>9 products at issue or what implication that has</p> <p>10 for the risk profile.</p> <p>11 Q. Do you have an opinion whether NDMA or</p> <p>12 NDEA are, in fact, contaminants?</p> <p>13 A. I do not.</p> <p>14 Q. Do you have an opinion whether NDMA or</p> <p>15 NDEA are mutagenic?</p> <p>16 A. I do not.</p> <p>17 Q. Do you have an opinion whether NDMA or</p> <p>18 NDEA are carcinogenic?</p> <p>19 A. I do not.</p> <p>20 Q. Do you have an opinion whether NDMA or</p> <p>21 NDEA are genotoxic?</p> <p>22 A. I do not.</p> <p>23 Q. Can you explain to me why you read and</p> <p>24 cited as reliance material the expert report of</p>
<p style="text-align: right;">Page 15</p> <p>1 continues, And I offer no opinion on whether the</p> <p>2 presence of NDMA or NDEA impurities rendered any</p> <p>3 of the at-issue VCDs adulterated or misbranded</p> <p>4 during the relevant time period.</p> <p>5 Did I read that correctly?</p> <p>6 A. You did.</p> <p>7 Q. And does it mean that you have no</p> <p>8 opinion whether NDMA or NDEA rendered the VCDs</p> <p>9 in this case adulterated or misbranded?</p> <p>10 A. That is correct. I am not offering</p> <p>11 opinions on whether the presence, or if there</p> <p>12 is, of NDMA and NDEA rendered the products at</p> <p>13 issue misbranded or adulterated.</p> <p>14 I have reviewed Dr. Conti's report and</p> <p>15 have opinions with respect to her valuation of</p> <p>16 the products at issue where she does make those</p> <p>17 assumptions, and I take her assumptions that she</p> <p>18 has made and consider them in my opinions. I do</p> <p>19 not offer an opinion on adulteration or</p> <p>20 misbranding.</p> <p>21 Q. Let me unpack that a bit.</p> <p>22 Do you have an opinion whether these</p> <p>23 contaminants were present at all in these VCDs?</p> <p>24 A. That is not a subject of my testimony</p>	<p style="text-align: right;">Page 17</p> <p>1 Dr. Ron Najafi?</p> <p>2 A. I released certain expert reports of</p> <p>3 various individuals that offered reports in this</p> <p>4 case, to gain an understanding of some of the</p> <p>5 background issues and scope.</p> <p>6 Some of the materials that I have</p> <p>7 reviewed were to inform me on the broader</p> <p>8 background materials and information that is at</p> <p>9 issue in this case. It does not mean I am</p> <p>10 offering opinions on all of the materials that I</p> <p>11 read.</p> <p>12 I don't recall offhand if I have cited</p> <p>13 Dr. Najafi in my report other than in mentioning</p> <p>14 him in paragraph 6.</p> <p>15 But if and where I have cited him, it</p> <p>16 will indicate the reasons for why I have relied</p> <p>17 on that report.</p> <p>18 Q. Well, why don't you turn to Exhibit 2</p> <p>19 of your report, which we are marking in this</p> <p>20 deposition as Exhibit 1, which lists the expert</p> <p>21 reports that you relied upon.</p> <p>22 Do you see that list?</p> <p>23 A. Yes.</p> <p>24 Q. I take your point about obtaining some</p>

<p style="text-align: right;">Page 18</p> <p>1 background information even as to areas that you 2 don't specifically offer an opinion. 3 But as best as you can, what was it 4 about Dr. Najafi's report that caused you to 5 list it as a reliance material? 6 A. I don't recall if there is specific 7 information from that report that I cite in my 8 background materials or later in my report. I 9 could page through it and see. 10 But as I sit here, I don't have a 11 specific recollection what caused me to list 12 that one in my materials considered. 13 Q. Do you recall what kind of expert 14 Dr. Najafi is? 15 A. No, not by memory. 16 Q. Can you tell me why you listed as 17 reliance material the expert -- 18 MR. GOLDBERG: Ruben, that question 19 cut out. You're going to have to ask it 20 again. 21 Q. Doctor, I'm asking you if you can tell 22 me why you listed reliance upon the report of 23 Dr. Panigraby. 24 A. I would give you essentially the same</p>	<p style="text-align: right;">Page 20</p> <p>1 doing so; right? 2 A. For the most part, that is correct. 3 The materials that appear on Exhibit 2 4 are materials that are cited throughout my 5 report. 6 It may be that there are certain 7 expert reports that are cited only in paragraph 8 6 and nowhere else. 9 And the reason they would appear on my 10 Exhibit 2 is that they appear in a footnote, 11 even if the footnote is no more than to identify 12 that report. 13 Q. Do you know what the subject of 14 Dr. Panigraby's report was? 15 A. Not by memory, no. 16 Q. Can you tell me why you listed the 17 report of Dr. Etminan as reliance material for 18 you? 19 A. The same answer. I reviewed various 20 expert reports. 21 If they are cited in my footnotes, 22 they are included on Exhibit 2. 23 There are some that may be cited only 24 in connection with paragraph 6 where I have</p>
<p style="text-align: right;">Page 19</p> <p>1 answer. 2 I don't recall specifically any 3 information from the report of Dr. Panigraby 4 that I rely on for my opinions. 5 If I cite him in the footnotes, then 6 that would indicate the information that I am 7 citing for that report. 8 If I don't and it was simply a report 9 that I reviewed in the context of getting 10 broader information, I don't recall why that one 11 in particular I chose to cite. 12 Q. Did you prepare this list of reliance 13 material yourself? 14 A. I have a person on my team that 15 prepares it for me. 16 Q. Okay. You mean physically prepares 17 the document? Is that what you mean? 18 A. Yes. 19 Q. Are you the one that's collected the 20 expert reports that you listed as reliance 21 material? 22 A. Yes. 23 Q. And so, I take it, since you were the 24 one to list them, that you had a reason for</p>	<p style="text-align: right;">Page 21</p> <p>1 listed some of the expert reports. 2 But if it is not cited elsewhere in 3 the report, it is not the basis for any of the 4 information or opinions that I am offering. 5 Q. Would your answer be the same for 6 Dr. David Chan, who is also listed as a report 7 you relied upon? 8 A. Yes. 9 Q. That's a rebuttal report. 10 Do you know what the subject of his 11 report was? 12 A. Not as I sit here without it in front 13 of me, I don't. 14 Q. Do you offer any opinions on cGMP? 15 A. I do not. 16 Q. Well -- but, Dr. Stiroh, is -- there 17 you go. 18 Dr. Stiroh, can you hear me? 19 A. Okay. My computer has a message that 20 says that my Internet connection is unstable. 21 I can hear you now. I think that cut 22 out in some -- at some point if you were asking 23 a question, and so if you could ask it again. 24 Q. I will. Thank you.</p>

<p style="text-align: right;">Page 22</p> <p>1 I asked you whether you offered any 2 opinions in the area of cGMP and cGMP 3 compliance. 4 MR. GOLDBERG: Objection to form. 5 A. I do not. 6 Q. Can you tell me why you listed the 7 expert report of Dr. -- or Mr. Quick in your 8 reliance material, plaintiffs' cGMP expert? 9 A. I reviewed the Quick report at the 10 time that I received it, I think in part to see 11 if there were opinions that related to economic 12 losses. 13 I don't recall anything specific in 14 his report that I rely on, unless there might be 15 a definition that I cite to him for. 16 Q. Was it meaningful for your economic 17 analysis to have an understanding of the 18 allegations regarding the cGMP failures in this 19 case? 20 MR. GOLDBERG: Objection to form. 21 Vague. 22 A. I reviewed his report. I don't recall 23 that there is anything specific that was 24 meaningful for me and my analysis of economic</p>	<p style="text-align: right;">Page 24</p> <p>1 A. I don't think that is fair to say. 2 As a general matter, damages experts 3 will take certain allegations in the complaint 4 at face value and consider, if they are true, 5 what are the economic damages that arise from 6 those actions, and also to consider as 7 appropriate, if some of the allegations are true 8 and others are not, whether damages can be 9 assessed with information common to the class. 10 I have considered the scope of 11 allegations. 12 I have considered how Dr. Conti refers 13 to the alleged wrongdoing and taken that 14 information into account when I formed my 15 opinions. 16 Q. In what way have you taken into 17 account the allegations in this case as they 18 pertain to cGMP failures? 19 A. I am going to have to tell you from 20 memory without looking at specific information. 21 To the best of my recollection, 22 Dr. Conti has a section in her report where she 23 either opines or assumes that if there is a cGMP 24 failure, that a drug is then misbranded or</p>
<p style="text-align: right;">Page 23</p> <p>1 loss damages. 2 But I did at the time that I reviewed 3 his report have a -- the understanding from 4 reading it what the subject matter was that he 5 was opining on. 6 Q. Did you give any weight or 7 consideration whatsoever to any of the opinions 8 of either Mr. Quick or the defense experts in 9 cGMP to your economic analysis? 10 MR. GOLDBERG: Objection to form. 11 Vague. Overbroad. 12 A. I don't recall anything by memory 13 where I am relying on or use as a basis an 14 opinion of any cGMP experts in this case. 15 I reviewed some pieces of information 16 to understand the context of the case, but I 17 don't think there is any of my opinions with 18 respect to economic loss damages that rely on a 19 cGMP expert's opinion. 20 Q. So would it be fair to say that if 21 there was pervasive cGMP failures on the part of 22 one or more of the defendants in this case, that 23 that did not impact any of your economic 24 analysis?</p>	<p style="text-align: right;">Page 25</p> <p>1 adulterated, and in her framework, that means 2 that for her, that the drug is economically 3 worthless. 4 I consider that chain of reasoning and 5 respond to it in my report. 6 Q. What consideration do you give it -- 7 the fact in your framework? 8 MR. GOLDBERG: Can you ask that again, 9 Ruben? You broke up. 10 Q. Yeah. You described understanding 11 that Dr. Conti in her report discusses and gives 12 some specific weight and consideration to the 13 fact of cGMP failures. 14 That's what you've told me; right? 15 A. I don't think it is what I told you. 16 I am not opining that there is a fact 17 of cGMP failures, and I don't think that 18 Dr. Conti did, unless I have misread her report. 19 I understand that she has taken it as 20 an assumption that there were cGMP failures, and 21 I consider the implication of that assumption 22 for her assessment of economic loss damages and 23 how I think economic loss damages would be 24 properly calculated if there are any in this</p>

<p style="text-align: right;">Page 26</p> <p>1 matter.</p> <p>2 Q. Did you assume that there were cGMP</p> <p>3 failures for your analysis?</p> <p>4 A. I don't have a specific assumption</p> <p>5 that there were cGMP failures.</p> <p>6 I take under consideration the</p> <p>7 possibility that the drugs would be considered</p> <p>8 misbranded or adulterated and consider how that</p> <p>9 impacts Dr. Conti's opinions.</p> <p>10 I understand that chain of reasoning</p> <p>11 in her report starts from an assumption of cGMP</p> <p>12 failures.</p> <p>13 I can't think as I sit here whether</p> <p>14 there are specific aspects of my opinions that</p> <p>15 depend on me making that assumption.</p> <p>16 Q. Well, so, before we move on from this</p> <p>17 idea, I am understanding with some clarity that</p> <p>18 you understood how Dr. Conti treated that in her</p> <p>19 framework.</p> <p>20 I'm simply trying to understand what</p> <p>21 you did with either the compliance or</p> <p>22 noncompliance of cGMP.</p> <p>23 How does that fit into your framework</p> <p>24 or analysis?</p>	<p style="text-align: right;">Page 28</p> <p>1 economic damages that flow from the conduct that</p> <p>2 is ultimately deemed to be wrongful.</p> <p>3 Q. Do you have analysis anywhere in your</p> <p>4 report that assumes liability and then</p> <p>5 determines if damages are calculable?</p> <p>6 MR. GOLDBERG: You're going to have to</p> <p>7 ask that again, Ruben. You broke up again.</p> <p>8 MR. HONIK: Did the court reporter get</p> <p>9 it?</p> <p>10 THE COURT REPORTER: I did not.</p> <p>11 Q. Is there any part of your report that</p> <p>12 assumes liability, as you've just described to</p> <p>13 me that damages experts sometimes do, in order</p> <p>14 to address damages?</p> <p>15 Is that something that you did?</p> <p>16 A. Yes.</p> <p>17 Q. And we'll certainly get more deeply</p> <p>18 into it.</p> <p>19 But where would I find that in your</p> <p>20 report, that is, your assumption of liability as</p> <p>21 a foundation for discussing damages? Where is</p> <p>22 that?</p> <p>23 A. There is nowhere in my report where I</p> <p>24 assume no liability.</p>
<p style="text-align: right;">Page 27</p> <p>1 MR. GOLDBERG: Objection to form.</p> <p>2 Vague. Compound.</p> <p>3 A. I do not offer opinions on whether</p> <p>4 there was compliance or noncompliance with cGMP.</p> <p>5 I offer opinions with respect to</p> <p>6 whether damages can be calculated with</p> <p>7 information common to the class and whether</p> <p>8 Dr. Conti has put forward a valid economic model</p> <p>9 to assess damages, if any, with information</p> <p>10 common to the class.</p> <p>11 Q. Is the fact of compliance with cGMP</p> <p>12 relevant to an economic analysis of damages in</p> <p>13 this case?</p> <p>14 A. For the analysis itself, whether there</p> <p>15 is compliance or noncompliance, may not be</p> <p>16 relevant in the following sense: That if there</p> <p>17 is ultimately no finding of wrongdoing, my</p> <p>18 understanding is that there is no damage,</p> <p>19 regardless of assumptions made by economists.</p> <p>20 At the stage where I as a damages</p> <p>21 expert am typically involved in a matter, there</p> <p>22 has not been a finding of wrongdoing in many</p> <p>23 cases, and so we would then consider, if there</p> <p>24 is a finding of wrongdoing, what are the</p>	<p style="text-align: right;">Page 29</p> <p>1 So in that sense, the entirety of my</p> <p>2 report assumes that liability will be found for</p> <p>3 some conduct.</p> <p>4 If liability is found for no conduct,</p> <p>5 I think my report generally becomes irrelevant.</p> <p>6 Q. Right. But my question is -- is</p> <p>7 specific.</p> <p>8 Can you point to any language in your</p> <p>9 report that I or any reader could find that says</p> <p>10 you've assumed liability on any basis in order</p> <p>11 to discuss or analyze economic damages?</p> <p>12 MR. GOLDBERG: Objection to form.</p> <p>13 Asked and answered.</p> <p>14 A. I don't recall having written that</p> <p>15 into my report.</p> <p>16 It is typically a standard</p> <p>17 going-forward assumption for a damages economist</p> <p>18 to consider the impact of certain acts where</p> <p>19 liability for those acts may be determined at a</p> <p>20 later stage by a court.</p> <p>21 Q. Okay. And I'm familiar with that</p> <p>22 construct as well.</p> <p>23 Is there someplace in your report</p> <p>24 where I could see your discussion of the basis</p>

<p style="text-align: right;">Page 30</p> <p>1 for that liability; in other words, whether the 2 basis lies in warranty or statutory -- 3 the -- for economic analysis? 4 Where would I find it in your report? 5 MR. GOLDBERG: You're going to have to 6 ask that again, Ruben. 7 MR. HONIK: Jeff, did you hear it? 8 THE COURT REPORTER: No. Part of it 9 cut out. 10 MR. HONIK: Okay. 11 Q. The question I'm trying to get at, 12 Dr. Stiroh, is this: Having read the -- 13 MR. GOLDBERG: Ruben, hang on for one 14 second. 15 Q. -- complaint and other -- 16 MR. GOLDBERG: Can we go off the 17 record for one second? I do have an idea. 18 MR. HONIK: Yeah, let's do that. 19 THE VIDEOGRAPHER: The time right now 20 is 10:42 a.m. We are off the record. 21 (Discussion off the record.) 22 THE VIDEOGRAPHER: The time now is 23 11:08 a.m. We are back on the record. 24 Q. Dr. Stiroh, thank you for your</p>	<p style="text-align: right;">Page 32</p> <p>1 liability on the basis of a warranty claim, does 2 that impact your analysis differently than 3 assuming, for example, that liability is 4 predicated on negligence? 5 MR. GOLDBERG: Objection to form. 6 Ambiguous. Calls for a legal conclusion. 7 A. It does not affect my analysis in any 8 way as I sit here. 9 To the extent that the legal framework 10 has different ways of considering economic 11 damages, that I would look for guidance from 12 counsel as to whether there are different 13 measures of economic damages depending on the 14 bases for liability, if any, is found. 15 Q. We'll talk about the basis for 16 measuring or the formulas for measuring. 17 But you agree those are legal 18 determinants; correct? 19 MR. GOLDBERG: Objection to form. 20 Ambiguous. 21 A. It is my understanding that it -- 22 there would be a legal determination as to 23 whether there is a basis for damages, yes. 24 Q. And before moving on, in connection</p>
<p style="text-align: right;">Page 31</p> <p>1 considerable patience. I am sorry it's taking 2 so long. And let's see how it goes. Okay? 3 A. Yes. 4 Q. I want to try to pick up where I think 5 we left off, and that is, we were discussing -- 6 I was attempting to understand what assumptions 7 you made around the liability questions. 8 You -- you have already described 9 yourself as a damage expert; correct? 10 A. Yes. 11 Q. And do you agree generally that the 12 basis for liability impacts damage analysis? 13 MR. GOLDBERG: Objection to form. 14 Vague. 15 A. I don't agree generally. 16 As a matter of economics, it may be 17 that it is the fact of liability on a particular 18 claim that then generates damages flowing from 19 that claim. 20 But as a legal basis, the basis for 21 liability I don't think I can tell you matters 22 without some specificity as to what it is that 23 you mean. 24 Q. So, for example, if you assume</p>	<p style="text-align: right;">Page 33</p> <p>1 with your analysis in your report, did you make 2 one or more assumptions about the basis for 3 liability in order to arrive at your economic 4 damages opinions? 5 A. I don't recall having done so. 6 I have considered the possibility that 7 there would be a finding that the products at 8 issue contain impurities. 9 And I have considered the assumptions 10 that Dr. Conti made and followed with my 11 economic analyses of damages in her framework 12 and the framework I put forward in my report. 13 Q. In the many cases in which you've been 14 asked to serve as an expert consultant in 15 litigation matters, you frequently need to make 16 assumptions, do you not, in order to answer 17 certain economic questions; correct? 18 A. I agree. 19 Q. And so, for example, I know one of 20 your particular -- I'll refer to it as a 21 subspecialty area is evaluating damages in the 22 antitrust context; correct? 23 A. I'm sorry. What was the question? 24 Q. The question is: You have</p>

<p style="text-align: right;">Page 34</p> <p>1 considerable expertise in analyzing economic 2 damages in the antitrust area; correct? 3 A. Yes. 4 Q. And I gather one of the things, for 5 example, by way of illustration, that you do 6 there is that you either yourself or you 7 evaluate others' assessments of a but-for world 8 with an actual world in terms of economic 9 consequences; correct? 10 MR. GOLDBERG: Objection to form. 11 A. That is a damage model that I am 12 familiar with, yes. 13 Q. That's right. 14 And in order to actions such models, 15 you have to make certain assumptions in order to 16 arrive at a reasonable understanding of what the 17 models propose; correct? 18 A. Yes. 19 Q. So you use things, for example, like 20 regression modeling; correct? 21 MR. GOLDBERG: Objection to form. 22 Vague. 23 A. I have used regressions in analyzing 24 things like economic damages or relevant</p>	<p style="text-align: right;">Page 36</p> <p>1 Q. Understood. Did you assume any of the 2 facts in the master complaints here? Did you 3 assume those allegations to be true? 4 A. I believe where appropriate I have. 5 I have not assumed that facts are not 6 true, as far as I can recall. 7 I have considered the economic 8 implications if there are impurities in the 9 drugs at issue. 10 There may be certain scenarios that I 11 consider that are different from what plaintiff 12 put forward, but that, to my mind, is different 13 from assuming the facts away. 14 Q. What allegations of plaintiffs' 15 economic loss complaint did you assume to be 16 true? 17 A. I understand that there is an 18 allegation that NDMA and NDEA impurities were 19 added in the manufacturing process for certain 20 of the Valsartan-containing drugs at issue. 21 I take -- I understand that there is 22 the allegation that then the FDA would not have 23 approved drugs with those impurities in them. 24 I take as given the market facts as I</p>
<p style="text-align: right;">Page 35</p> <p>1 markets, as they are relevant to work that I 2 have done. 3 Q. Have you had occasion to do economic 4 or damage analysis based on assumptions or 5 representations about legal rulings, or based on 6 legal rulings? 7 A. Yes. 8 Q. And, in fact, for example, in the 9 antitrust area, have you had occasions where 10 you've been asked to assume or you've been told 11 that courts have determined that there's 12 antitrust culpability and antitrust impact, and 13 then the question becomes how to assess the 14 damages related thereto? Have you done that? 15 A. I have not in my experience in 16 antitrust matter. 17 Whether there's antitrust impact is a 18 question for economic testimony, and it's a 19 question on which I have opined. 20 In the antitrust scenario, it would be 21 common for a damage expert to assume the facts 22 in a complaint with respect to conduct are true, 23 but not to assume impact of that conduct without 24 analyzing it in a framework of economics.</p>	<p style="text-align: right;">Page 37</p> <p>1 understand them that the drugs at issue were 2 withdrawn in 2018 and '19. 3 I take as my understanding that there 4 is a dispute over whether the impurities at 5 issue enhanced any risk that a patient would 6 face, and I consider that aspect of the dispute, 7 taking into account both the possibility that 8 the impurities at issue would have increased 9 risks to patients and the possibility that the 10 impurities at issue would not have increased 11 risk to patients. 12 And I explain in my report how that 13 variation flows through into assessing economic 14 damages. 15 Q. What do you mean when you say that you 16 assumed the FDA would not have approved the 17 drugs, in your response? 18 A. I consider the framework that I 19 understand Dr. Conti to have put forward where 20 she says there would not have been a supply of 21 the products at issue. 22 To the best of my recollection, I 23 think that she is assuming that from 2012 24 forward, whereas the market facts as I</p>

<p style="text-align: right;">Page 38</p> <p>1 understand them is that the products at issue 2 were not available in 2018 and 2019. 3 Q. Where in your report would it reveal 4 to me or any reader that you assumed the fact 5 you just described? 6 A. There is a section in my report where 7 I discuss what consumers would have done in the 8 absence of the availability of the VCDs at 9 issue. 10 That is consistent with the framework 11 that Dr. Conti has put forward where she assumes 12 that there would not be supply of the products 13 at issue. 14 Q. Where is that analysis in your report? 15 A. It is included at various places in my 16 report as appropriate, and specifically in 17 section Roman Numeral IV of my report, the 18 discussion begins on paragraph 26. 19 I have discussed various aspects, I 20 think, that are aligned with that theory, what 21 if the drugs were not available at other places 22 as well. But at least Roman Section IV. 23 Q. So I want to make sure that you and I 24 are on the same page.</p>	<p style="text-align: right;">Page 40</p> <p>1 III where I also consider what patients would 2 have done in the absence of available supply for 3 VCDs at issue. 4 But the part that I recall discussing 5 it more explicitly is Roman IV. 6 Q. Would section Roman IV of your report, 7 in addition to the other sections to which 8 you've cited me, reflect your analysis of 9 potential damages in the absence of a supply 10 curve for VCDs? 11 A. My analysis in section IV reflects a 12 consideration of the financial losses in the 13 absence of supply for the VCDs at issue. 14 Q. Do you assume in your analysis found 15 in section IV that there is an absence of a 16 supply curve for VCDs? 17 A. I do not assume an absence of a supply 18 curve for VCDs. 19 I understand that one of the 20 alternatives available to consumers in the 21 absence of the at-issue VCDs would have been the 22 brand drug and I think some supply available 23 from other manufacturers that are not 24 defendants.</p>
<p style="text-align: right;">Page 39</p> <p>1 My Roman IV is headed, Plaintiffs' 2 payments for VCDs and VCD substitutes would 3 likely have been equal or higher. 4 Is that the section you're directing 5 me to? 6 Because that comports with paragraph 7 50, 5-0, in my report. 8 A. Yes. Did I say a different number? I 9 meant to say page 26, paragraph 50. 10 Q. Got it. 11 Are there any other discrete places in 12 your report that you believe discusses assuming 13 that the FDA would not have approved these 14 drugs, and, therefore, they wouldn't have been 15 in the marketplace? 16 Where else do you discuss it? 17 MR. GOLDBERG: Objection to form. 18 Mischaracterizes the testimony. 19 A. I think all of Roman IV, which goes 20 over to a chart that is on page 34. 21 But there may be other places, 22 certainly in the summary of opinions that's at 23 the beginning of my report. 24 And then there may be parts of Roman</p>	<p style="text-align: right;">Page 41</p> <p>1 Q. Is there any part of your analysis in 2 which you assume an absence of a supply curve 3 for contaminated VCDs? 4 A. In my section Roman IV, I consider 5 what the economic implications are if there had 6 not been supply of contaminated VCDs. 7 Q. And was your conclusion in that 8 section, generally speaking, that patients would 9 go to alternative drug therapy? 10 A. Did you ask me if that was my 11 conclusion? 12 Q. Yes. 13 A. It is not a conclusion that I have. 14 It is a consideration that I have. 15 My understanding is that patients that 16 are currently on VCDs or blood pressure 17 medication, if they could not take their current 18 medication, would for the most part be required 19 to switch to something else. 20 I have seen in the data that there are 21 some patients that appear to have switched to 22 things like Vitamin C. 23 So I don't assume that everybody needs 24 to switch, but it is my understanding that the</p>

<p style="text-align: right;">Page 42</p> <p>1 majority of consumers would need to take a 2 medication to manage their blood pressure. It 3 is not necessary to my conclusions that all of 4 them do. 5 Q. Are you aware that "adulterated" is a 6 term of art with a specific definition under the 7 Federal Food, Drug and Cosmetic Act? 8 A. My understanding is that it is. 9 Q. And did you list the relevant section 10 that defines "adulterated" among your reliance 11 materials? 12 A. I don't think that I did. I did not 13 rely on an FDA statement of adulteration. I 14 have considered what Dr. Conti considered in her 15 report, and my report responds to her opinions. 16 Q. Well, do you acknowledge that 17 Dr. Conti merely applied the definition of 18 "adulterated" as the FDA in the Federal Food, 19 Drug and Cosmetic Act sets it out? 20 A. As I recall from her report, I believe 21 that is what she sets out to do. 22 I did not go to check whether she had 23 cited it correctly or interpreted it correctly. 24 I take the words in her report as given and</p>	<p style="text-align: right;">Page 44</p> <p>1 mean? 2 A. As appreciated by that consumer and/or 3 their doctor. 4 Q. Okay. You listed in your reliance 5 material at Exhibit 2, which is now part of your 6 report at Exhibit 1, four court filings. 7 Do you see that? 8 A. Yes. 9 Q. There are roughly 2,000 court filings 10 in this MDL. 11 Why did you pick these four? 12 A. The four that are cited here are the 13 ones that I cited in my report for -- as the 14 basis for certain statements or quotes that I 15 have taken from those court filings. 16 Q. Yeah. That strikes me as a tautology. 17 They're there because you cite them in your 18 report. 19 My question is, Why did you select 20 these four? 21 How are they relevant to your analysis 22 and opinions? 23 A. We can see from where I have cited 24 them how they fit in.</p>
<p style="text-align: right;">Page 43</p> <p>1 consider the implications for economic loss 2 damages. 3 Q. What are the implications, in your 4 judgment, for economic loss damages that we may 5 be dealing with and, in fact, are dealing with 6 adulterated drugs? 7 MR. GOLDBERG: Objection to form. 8 Assumes facts not in evidence. Ambiguous. 9 A. As an economic matter, the economic 10 losses that relate to the difference between the 11 price paid and the value received depend on the 12 impact on the value received by consumers of 13 VCDs from having consumed a product that has an 14 impurity in it that caused it to be deemed 15 adulterated or misbranded. 16 As I explained in my report, as a 17 matter of economics, that diminution of value, 18 if any, depends on what I think I have called 19 the degree of adulteration. By that, I mean 20 depends on how the risk profile of the product 21 may change for any consumer consuming the 22 product. 23 Q. And would that be the risk profile as 24 appreciated by that consumer? Is that what you</p>	<p style="text-align: right;">Page 45</p> <p>1 The definition of the class -- of the 2 purported class, the identities of defendants, 3 the identities of the named plaintiffs all come 4 from the complaint. And so that is cited. 5 There are certain background facts 6 where I understand there may be a dispute, but 7 from my -- for my purposes, I am using a 8 particular definition, and frequently I will 9 cite a definition that comes from the complaint 10 or the opposing party, if -- if relevant, so 11 that there is not dispute over that fact, and, 12 instead, I focus on the economic analyses. 13 Q. Were these four court filings provided 14 to you by counsel and suggested as material you 15 should rely on, or did you have a larger pool of 16 documents from which you selected these four on 17 your basis? 18 A. I have a larger pool of documents and 19 selected these four as having information that I 20 wanted to put either in the background of my 21 report or to define what has been put forward as 22 the class, the dates of the class, the 23 identities of the parties, things like that. 24 Q. I note that you didn't rely on any</p>

<p style="text-align: right;">Page 46</p> <p>1 opinions or writings of the court to shed light 2 on either the theories or the appropriate 3 measure of damages. 4 Why didn't you do that? 5 A. I have been asked to assess from the 6 standpoint of an economist what -- whether 7 economic loss damages in the -- for the class 8 members as described in the motion for class 9 certification can be assessed with information 10 methods common to the class. 11 I did that based on my training as an 12 economist, and have explained at certain places 13 in my report where I understand there to be a 14 correspondence of legal theories and economic 15 theories. 16 But for the most part, my report is an 17 independent economic analysis of economic loss 18 damages. 19 Q. Yeah, I understand all that. 20 But my question was very specific, and 21 that was, why didn't you look at any of the 22 writings of the court in the form of opinions to 23 shed light on any issues that may impact that 24 economic analysis and the ability to certify a</p>	<p style="text-align: right;">Page 48</p> <p>1 Q. Were you told not to assume that the 2 court's opinions are reliable? 3 A. I was not. 4 MR. GOLDBERG: Objection. Note my 5 objection to that question as ambiguous. 6 Q. What opinions of the court did you 7 read that you failed to list in your reliance 8 materials list? 9 A. I did not fail to list any opinions in 10 my reliance list, because I did not rely on 11 opinions for the court. 12 I recall reviewing an opinion of the 13 court. I believe there are more than one. I 14 can't recall them for you with certainty as I 15 sit here without them in front of me. 16 I think Dr. Conti refers to them 17 either in her report or in her deposition, and 18 it would be those ones that are referenced that 19 I have reviewed. 20 Q. So these opinions that you did review, 21 it sounds like you reviewed them after you wrote 22 your report; correct? 23 A. I have reviewed them after I wrote my 24 report. To the best of my recollection, I have</p>
<p style="text-align: right;">Page 47</p> <p>1 class for damages? 2 MR. GOLDBERG: Objection to form. 3 Asked and answered. 4 A. In the course of my work on this case, 5 I have reviewed other legal documents, including 6 opinions of the court. For the purposes of my 7 opinions that relate to economic losses, and 8 whether there are economic losses that can be 9 calculated on a class-wide basis, I rely on my 10 training and experience as an economist and 11 review the types of information that are 12 available in this case that economists typically 13 rely upon. 14 Q. So you did review opinions in the 15 court, you just didn't list them as reliance 16 materials; right? 17 A. I reviewed opinions of the court. I 18 did not rely on an opinion of the court to reach 19 my independent conclusions as an economist. 20 Q. When you say "independent," what do 21 you mean by that? 22 A. I mean that I have not been asked to 23 assume somebody else's opinion is true. I have 24 been asked to reach my own opinions.</p>	<p style="text-align: right;">Page 49</p> <p>1 seen the opinions of the court prior to writing 2 my report as well. 3 Q. What opinions of the court did you 4 review prior to the preparation and tendering of 5 your report that would not be listed in your 6 reliance materials list? 7 A. I don't recall by title opinions of 8 the court that I reviewed prior to my report. 9 There are no opinions of the court 10 listed in my reliance materials because I did 11 not rely on opinions of the court in reaching my 12 economic opinions. 13 Q. Right. I understand that you didn't 14 rely on anything the court has said. 15 Now I'm trying to identity what you, 16 nonetheless, read that the court opined on prior 17 to January 12th of this year, which is the date 18 of your report. 19 If you don't remember the titles or 20 formal names of the opinions, tell me what the 21 subjects were. 22 A. To the best of my recollection, the 23 subjects are motions to dismiss documents where 24 the court has written a document that I think</p>

<p style="text-align: right;">Page 50</p> <p>1 the title has opinion in it.</p> <p>2 Q. Okay. And is it correct that when you</p> <p>3 read the motions to dismiss, there was nothing</p> <p>4 in there that the court shed light on which</p> <p>5 impacted your economic analysis or damage</p> <p>6 analysis?</p> <p>7 MR. GOLDBERG: Objection. Ambiguous.</p> <p>8 A. I don't recall if there was anything</p> <p>9 in them that shed light on my economic analysis.</p> <p>10 To the extent that there was something</p> <p>11 that is consistent with other documents that I</p> <p>12 have read that shed light on my economic</p> <p>13 analysis, I have relied on materials and</p> <p>14 information that are commonly relied upon by</p> <p>15 economists in reaching independent economic</p> <p>16 opinions, and I have not relied on an opinion of</p> <p>17 the court to reach my own opinion.</p> <p>18 Q. So if the court offered an opinion</p> <p>19 about the viability of a certain cause of action</p> <p>20 alleged in plaintiffs' complaint and the</p> <p>21 economic impact of that, you did not place any</p> <p>22 weight or reliance on such views; correct?</p> <p>23 A. I think it is not correct to phrase</p> <p>24 what I did in that way.</p>	<p style="text-align: right;">Page 52</p> <p>1 reviewed opinions of the court connected with</p> <p>2 motions to dismiss.</p> <p>3 To the best of my recollection, they</p> <p>4 are the same that I had reviewed earlier in the</p> <p>5 case. They are not things that I relied upon to</p> <p>6 reach my opinions.</p> <p>7 Q. Okay. And so if I've understood you,</p> <p>8 what you're saying is, you read opinions of the</p> <p>9 court on motions to dismiss both before and</p> <p>10 after you wrote your report, and in neither</p> <p>11 instance do you place reliance on the court's</p> <p>12 views; correct?</p> <p>13 MR. GOLDBERG: Objection.</p> <p>14 Mischaracterizes the testimony.</p> <p>15 A. For purposes of reaching my opinions</p> <p>16 with respect to the economic loss damages</p> <p>17 purportedly suffered by the class, I did not</p> <p>18 rely on a judge's legal opinion.</p> <p>19 I relied on my own training as an</p> <p>20 economist and the materials that an economist</p> <p>21 would typically consider in evaluating whether</p> <p>22 damages can be assessed with information and</p> <p>23 methods common to the class.</p> <p>24 Q. What do you mean by typically rely</p>
<p style="text-align: right;">Page 51</p> <p>1 I reviewed certain court documents.</p> <p>2 The opinion of the court that I have read does</p> <p>3 not -- is not something that I relied on in</p> <p>4 reaching my own opinions with respect to</p> <p>5 economic loss damages.</p> <p>6 Q. Did you read Dr. Conti's deposition</p> <p>7 testimony in preparation for today?</p> <p>8 A. I did.</p> <p>9 Q. What opinions were you shown or did</p> <p>10 you review after the preparation of your written</p> <p>11 report?</p> <p>12 You've only authored one written</p> <p>13 report; correct?</p> <p>14 A. In connection with this matter, that</p> <p>15 is correct.</p> <p>16 Q. When you say "in connection with this</p> <p>17 matter," have you authored any other writings in</p> <p>18 connection with this MDL which concerns</p> <p>19 Valsartan, Losartan and Irbesartan?</p> <p>20 A. I have not.</p> <p>21 Q. So the question is, What opinions of</p> <p>22 the court did you read and/or consider after the</p> <p>23 preparation of your one and only written report?</p> <p>24 A. To the best of my recollection, I have</p>	<p style="text-align: right;">Page 53</p> <p>1 upon?</p> <p>2 What do economists typically rely upon</p> <p>3 that you place reliance on to the exclusion of</p> <p>4 the court's views?</p> <p>5 A. I do not exclude the court's views. I</p> <p>6 did not rely on the court's views for purposes</p> <p>7 of my -- of reaching my opinions.</p> <p>8 The things that I rely upon, as I</p> <p>9 mentioned, my training and experience as an</p> <p>10 economist, that is, the economic -- the</p> <p>11 application of economic theory and models to</p> <p>12 business situations to assess whether there is</p> <p>13 economic loss to individuals in a given set of</p> <p>14 circumstances.</p> <p>15 Q. Does it matter to you to understand</p> <p>16 what the court's views about what the proper</p> <p>17 measure of damages is to do the work you were</p> <p>18 asked to do?</p> <p>19 MR. GOLDBERG: Objection to form.</p> <p>20 Ambiguous.</p> <p>21 A. To do the work that I was asked to do</p> <p>22 is what I have in my report.</p> <p>23 I was asked to assess whether damages</p> <p>24 could be determined on a class-wide basis with</p>

<p style="text-align: right;">Page 54</p> <p>1 information common to the class where those 2 damages were economic loss damages. 3 I have explained in my report the 4 framework that I am using for economic loss 5 damage. 6 To carry out my assignment in this 7 case, it was not necessary to take an 8 assumption -- sorry -- to take an opinion of the 9 court as an assumption in reaching my economic 10 opinions. 11 Q. You wrote, and I quote, I also do not 12 opine on the legal issues relating to the proper 13 measure of damages or on which measures should 14 be used. 15 Do you remember writing that? 16 A. Yes. 17 Q. Does it matter to you whether the 18 court has a view or opinion on what the proper 19 measure of damages is or which measure should be 20 used? Is that relevant to you? 21 A. I would anticipate, in the fullness of 22 time, the court will eventually reach an opinion 23 on the proper measure of damages to be used, and 24 my report is something that I have been asked to</p>	<p style="text-align: right;">Page 56</p> <p>1 being asked to give my opinions on economic loss 2 damages. 3 Q. If you were told to assume VCDs in 4 this case were adulterated under the meaning of 5 the Food, Drug and Cosmetic Act, would that have 6 changed any of your opinions in this case? 7 A. No. 8 Q. I'm sorry. Did you say no? 9 A. I did say no. 10 Q. Did you consider in any way in your 11 economic analysis whether if the VCDs in 12 question were adulterated as defined under that 13 act, what impact it would have on your economic 14 analysis and various conclusions? 15 A. The question was, did I consider that? 16 THE WITNESS: I'm sorry, Jeff. If you 17 don't mind reading that one back to me as 18 well. 19 Q. I'll restate it. 20 Did you consider in any way in your 21 economic analysis whether if the VCDs in 22 question were, in fact, adulterated as defined 23 under the Food, Drug and Cosmetic Act, if that 24 would influence or impact any of your economic</p>
<p style="text-align: right;">Page 55</p> <p>1 prepare that reflects my opinions on those 2 topics. 3 Q. If the fullness of time were to have 4 occurred already and it coincided with today, 5 and if you were told today what the court said 6 is the proper measure of damages, or which 7 measure should be used, would you accept that 8 and rely upon it in forming opinions? 9 A. I'm sorry. I need you to say the 10 beginning of that again. I missed at least one 11 of the words in your question. Not a technology 12 issue. I just didn't hear it. 13 MR. HONIK: Jeff, did you get my 14 question? 15 THE COURT REPORTER: Yes, I did. 16 MR. HONIK: Would you be kind enough 17 to read it to Dr. Stiroh. 18 THE COURT REPORTER: Sure. 19 (The record was read back.) 20 A. I would not, for the reason that if 21 the court has fully determined what the measure 22 of damages is and does not require, or the 23 parties do not believe, that there is any role 24 for opinion testimony, I would not anticipate</p>	<p style="text-align: right;">Page 57</p> <p>1 analysis or conclusions? 2 MR. GOLDBERG: Objection. Vague. 3 Overbroad. 4 A. I have considered that scenario. 5 It does have an impact on my damages 6 assessment. 7 If it is not -- if the products at 8 issue are not found to be adulterated or 9 misbranded, my understanding is there would then 10 be no damages arising from the conduct at issue. 11 If their products at issue are found 12 to be adulterated and misbranded, then, as I 13 explained in my report, to an economist 14 assessing diminution of value that comes from 15 adulteration or misbranding, it matters the 16 degree to which any product consumed by any 17 consumer was adulterated or misbranded, the 18 impact that that adulteration has for the 19 efficacy of the drug for that consumer, whether 20 it still has a therapeutic benefit to the 21 consumer, the amount of the product that they 22 consumed, the change in the risk profile for the 23 consumer, and I understand that some of those 24 factors depend on things individual to the</p>

<p style="text-align: right;">Page 58</p> <p>1 consumer, such at their weight and health 2 history. 3 Q. What is the proper measure of damages 4 for a contaminated drug in the U.S. supply 5 chain? 6 MR. GOLDBERG: Object to form. Calls 7 for a legal conclusion. 8 A. I'm not offering an opinion on what 9 the proper measure of damages is. I'm offering 10 opinions on how to properly use economics to 11 assess damages when those damages come from 12 diminution of loss or differences in financial 13 circumstances of patients. 14 Q. What is the difference between the 15 phrases you used, "proper measure of damages," 16 versus "which measure should be used"? 17 Are those terms synonymous or 18 different? 19 A. They are different. 20 Q. Can you tell me the difference. 21 A. Yes. In my report when I use "proper 22 measure of damages," I am speaking from the 23 standpoint of an economist how to use economics 24 properly in the measure of damages.</p>	<p style="text-align: right;">Page 60</p> <p>1 they synonymous as you've used them? 2 A. They're not synonymous as I have used 3 them. I think that the explanation that I gave 4 you a minute ago is correct. 5 I don't know with certainty, but it 6 would not surprise me if elsewhere in the report 7 I have used the phrase "to properly calculate 8 economic damages" or "a proper measure of 9 economic damages," or even just "a proper 10 measure of damage" with the word "economic" 11 elsewhere in the sentence. 12 When I use "proper measure of damages" 13 elsewhere in my report, I'm opining on 14 economics. 15 In this sentence that you have quoted 16 that is towards the end of paragraph 5, I am 17 clarifying that if there are legal issues that 18 relate to the proper measure of damages as I 19 would calculate them, I am not opining on the 20 legal issues and I am not opining on which 21 measure should be used. 22 Q. So do you accept that legal issues can 23 impact the proper measure of damages in a case 24 such as this?</p>
<p style="text-align: right;">Page 59</p> <p>1 I am not opining to the court on which 2 measure of damages, and in my report, I consider 3 alternative approaches to damage valuation. 4 Q. Okay. So what is -- what is "which 5 measure should be used," how is that different? 6 A. As I hear you say that, I -- I 7 understand that to mean am I telling the court 8 which measure should be used, and that is not 9 what I am intending to do. 10 Q. Okay. I think there's some confusion, 11 and I apologize. 12 I am directing your attention to 13 paragraph 5 of your own report, marked as 14 Exhibit 1, in which you write in the penultimate 15 sentence, quote, I also do not opine on the 16 legal issues relating to the proper measure of 17 damages or on which measure should be used. 18 Do you see that clause? 19 A. I do. 20 Q. And my question is, are those two 21 different things, the proper measure of damages 22 on the one hand, and which measures should be 23 used on the other? 24 Are they two different concepts or are</p>	<p style="text-align: right;">Page 61</p> <p>1 MR. GOLDBERG: Objection to form. 2 A. I don't have an opinion on that. 3 Q. Listen to my question. 4 Do you accept that legal issues may 5 have an impact on how and what the proper 6 measure of damages is in this case? 7 MR. GOLDBERG: Objection to form. 8 Vague. 9 A. I accept that there would be legal 10 issues that could determine which measure of 11 damages would be used. 12 As we've just had in our exchange, 13 when I use "proper measure of damages," I have 14 in that an expectation that it is properly using 15 economics, an economic theory. 16 When you asked the question, it sounds 17 like you maybe have a different measure or 18 definition that is the legal theory. 19 And what I've intended to do in the 20 sentence that you've quoted in paragraph 5 is 21 say specifically, that is not the subject I am 22 opining on. I am opining on economic damages, 23 and I do have an opinion on how economics would 24 properly be used in determining economic</p>

<p style="text-align: right;">Page 62</p> <p>1 damages.</p> <p>2 Q. Right. And I'm only trying to</p> <p>3 understand to what extent, if any, you accept or</p> <p>4 allow that legal principles and legal</p> <p>5 conclusions in a case like this impact your</p> <p>6 economic measure of damage analysis.</p> <p>7 A. I guess I am not following your</p> <p>8 question, then, or would need it explained.</p> <p>9 I have written a report that gives my</p> <p>10 opinions. I would expect the court would take</p> <p>11 into account economic opinions as well as legal</p> <p>12 information.</p> <p>13 I do not have an opinion with respect</p> <p>14 to the legal framework. I have opinions with</p> <p>15 respect to the economic framework.</p> <p>16 If the court takes into account</p> <p>17 different information, and particularly a legal</p> <p>18 framework, I think that affects what the court</p> <p>19 does with my opinion. It does not affect my</p> <p>20 opinions, unless you give me an example that</p> <p>21 then I can consider.</p> <p>22 Q. So is it your testimony that the legal</p> <p>23 framework, to borrow your phrase, doesn't impact</p> <p>24 your economic analysis?</p>	<p style="text-align: right;">Page 64</p> <p>1 statutory prejudgment interest rate, and I have</p> <p>2 taken those cases -- where appropriate, I have</p> <p>3 taken the statutory interest rate and used it in</p> <p>4 analyses.</p> <p>5 I don't know -- I can't think of an</p> <p>6 example like that that is relevant here.</p> <p>7 Q. Does it matter to you when the point</p> <p>8 of injury occurred in this case?</p> <p>9 MR. GOLDBERG: Objection to form.</p> <p>10 Vague.</p> <p>11 A. It does.</p> <p>12 Q. In what way?</p> <p>13 A. I understand that the allegations</p> <p>14 include an allegation that the VCDs at issue</p> <p>15 increase the risk profile of a potentially</p> <p>16 adverse health outcome for patients that consume</p> <p>17 them.</p> <p>18 I understand that the change in the</p> <p>19 risk profile depends on factors such as the</p> <p>20 amount of the -- of the products at issue that</p> <p>21 were consumed, the weight of the person</p> <p>22 consuming them, and other health factors. Those</p> <p>23 can change over time.</p> <p>24 I have an analysis in my report that</p>
<p style="text-align: right;">Page 63</p> <p>1 A. It is my understanding that a court</p> <p>2 may take into account things other than</p> <p>3 economics in assessing damages.</p> <p>4 The things that I take into account</p> <p>5 are economic variables.</p> <p>6 I have in my report explained why I</p> <p>7 have an understanding that some of the</p> <p>8 approaches that I describe may also be of</p> <p>9 relevance to the court. I am not telling the</p> <p>10 court which ones to consider.</p> <p>11 Q. Yeah. Dr. Stiroh, respectfully,</p> <p>12 you've turned the question on its head.</p> <p>13 I have a well-developed understanding</p> <p>14 of what courts consider.</p> <p>15 What I have asked you is whether, in</p> <p>16 your economic analysis and your opinions, you</p> <p>17 considered the legal framework, as you used that</p> <p>18 term.</p> <p>19 MR. GOLDBERG: Objection to form.</p> <p>20 Argumentative. Asked and answered.</p> <p>21 A. I don't have a basis to incorporate a</p> <p>22 legal framework into my analysis.</p> <p>23 I am not a lawyer. I have worked on</p> <p>24 matters where, for example, there is a -- a</p>	<p style="text-align: right;">Page 65</p> <p>1 considers the available information on how long</p> <p>2 and how many and of what concentrations of the</p> <p>3 products at issue certain class members took.</p> <p>4 That timeframe comes into account in</p> <p>5 assessing whether damages can be determined on a</p> <p>6 class-wide basis with information common to the</p> <p>7 class.</p> <p>8 Q. Did you give any consideration to when</p> <p>9 the drugs were purchased in time, to your</p> <p>10 economic analysis?</p> <p>11 A. I --</p> <p>12 MR. GOLDBERG: Objection.</p> <p>13 A. I think my answer just -- I think my</p> <p>14 answer answered that question.</p> <p>15 It -- my understanding is that the</p> <p>16 class period for the consumers and TPPs starts</p> <p>17 in 2012 and goes to the recalls.</p> <p>18 And I consider that patients are</p> <p>19 differently situated over that timeframe, that</p> <p>20 there are potentially class members who have</p> <p>21 taken the products at issue for longer periods</p> <p>22 than others. And I describe that in my report.</p> <p>23 Q. You listed the plaintiffs' economic</p> <p>24 loss complaint, as well as our memorandum of law</p>

<p style="text-align: right;">Page 66</p> <p>1 supporting class certification, as items that 2 you read and relied upon; correct? 3 A. Yes. 4 Q. Did you glean from any of that when 5 the plaintiffs allege that the economic harm 6 occurred? 7 And I don't mean the class period. I 8 mean, when was economic harm occurring for each 9 class member? Did you glean that? 10 A. Are you asking me about the economic 11 loss damages to the purported class of 12 consumers? 13 Q. Yes. 14 MR. GOLDBERG: Objection to form. 15 A. It is my understanding that the harm 16 to consumers is alleged to come from consumption 17 of the products at issue. 18 The products at issue were -- 19 Q. And when you -- I apologize. I spoke 20 over you. Go ahead. 21 A. The product at issue were consumed in 22 different amounts, in different quantities, and 23 over different frame -- timeframes by the class, 24 and I have considered that in my report.</p>	<p style="text-align: right;">Page 68</p> <p>1 the retailer? 2 A. It is not my understanding that those 3 are unrelated. 4 Q. Well, how is that related to your 5 analysis of the economic harm here? 6 A. My consideration of economic harm 7 includes a consideration of the difference 8 between the price paid, which would be the price 9 that was paid at retail, for example, for the 10 products at issue, and the value received. 11 And the value received would be the 12 value that a patient who consumed the product 13 received from consuming it. 14 Q. So the definition of value in that 15 sentence and in your analysis is the therapeutic 16 value that was given or provided to the patient; 17 correct? 18 A. It includes the therapeutic value that 19 was provided to the patient, yes. 20 Q. What else is included in your 21 definition of value in that construct? 22 A. The -- other factors that could be 23 considered in value to a patient that consumes 24 it are the either presence or lack of side</p>
<p style="text-align: right;">Page 67</p> <p>1 Q. When you say "consumption," do you 2 mean ingest? 3 A. I do. Sorry about that. I do. 4 Q. Did you in any way, shape or form 5 consider that the economic harm is unrelated to 6 consumption, but related to the purchase of the 7 drug? 8 A. I understand that the allegations of 9 harm to TPPs are not related to their 10 consumption of the drug. 11 I understand that the allegations of 12 harm to consumers comes from the fact that they 13 have consumed a drug that includes impurities. 14 If a consumer did not consume it or 15 purchased it on behalf of somebody else, a -- a 16 parent for a child, for example, I understand 17 that it is considering the harm for -- on the 18 consumers to the person that consumed the drug. 19 Q. Is it your understanding, therefore, 20 that the economic harm claimed in the economic 21 loss complaint on behalf of the consumer class 22 is unrelated to the purchase of the drug, that 23 is, the transaction at the retail level in which 24 some monies is exchanged between consumer and</p>	<p style="text-align: right;">Page 69</p> <p>1 effects from consuming the product at issue, the 2 effectiveness of the drug that they have 3 experienced relative to perhaps taking other 4 blood pressure medications, the ease with which 5 they can take it and remember to take it on a 6 particular daily, weekly, timeframe. 7 Whether they are obtaining it through 8 a mail order and it comes to their house versus 9 they have to drive to get it. 10 There may be other things, but those 11 are the ones that come to mind. 12 Q. Are you able to assign economic values 13 to the elements that you just laid out for me? 14 A. Can you say what you mean by "assign 15 economic value"? 16 Q. Yeah. Assign a cash value to it, a 17 dollar value to the elements you just described 18 as making up value. 19 MR. GOLDBERG: Objection to form. 20 Ambiguous. Overbroad. 21 A. From the standpoint of economic 22 theory, things that give value to a consumer can 23 be measured in dollar terms. 24 Q. Okay. Have you done that in your</p>

<p style="text-align: right;">Page 70</p> <p>1 analysis and report?</p> <p>2 A. I have not assessed the value of the</p> <p>3 products received on a</p> <p>4 class-member-by-class-member basis.</p> <p>5 My report and opinions of this class</p> <p>6 certification stage of the case includes the</p> <p>7 opinion that such an analysis requires</p> <p>8 individual information and cannot be performed</p> <p>9 on a class-wide basis.</p> <p>10 Q. Is there a reliable methodology of</p> <p>11 which you're aware that can place a dollar value</p> <p>12 on any of the elements of value that you've</p> <p>13 described to me?</p> <p>14 A. In a general sense, there are economic</p> <p>15 methods that have been used to assess changes in</p> <p>16 consumer welfare that to an economist means all</p> <p>17 of the aspects of value that a consumer would</p> <p>18 obtain.</p> <p>19 To assess damages or loss of consumer</p> <p>20 welfare in this matter, the diminution of value</p> <p>21 to a consumer depends on factors that are unique</p> <p>22 to a consumer and are not market-wide.</p> <p>23 So information in this matter would</p> <p>24 be, you would need individual-by-individual</p>	<p style="text-align: right;">Page 72</p> <p>1 hypothetical in your question.</p> <p>2 It had in it at the beginning, as I</p> <p>3 heard it --</p> <p>4 Q. I'll restate it for you. I'll restate</p> <p>5 it for you.</p> <p>6 I want you to assume that a court and</p> <p>7 a jury has concluded that the damages in this</p> <p>8 case total \$4 billion, which is the actual money</p> <p>9 paid by consumers and insurers for these</p> <p>10 contaminated drugs.</p> <p>11 You with me so far?</p> <p>12 A. Yes.</p> <p>13 Q. And I want you to further assume that</p> <p>14 the court will allow some evidence to diminish</p> <p>15 that number by value that the consumers or the</p> <p>16 TPPs received.</p> <p>17 Tell me how you would measure that and</p> <p>18 offer it as a -- what to deduct the \$4 billion</p> <p>19 number I asked you to assume.</p> <p>20 MR. GOLDBERG: Objection to form.</p> <p>21 Ambiguous.</p> <p>22 A. I don't understand your hypothetical.</p> <p>23 In my experience, if a jury has</p> <p>24 reached an opinion and conclusion that is after</p>
<p style="text-align: right;">Page 71</p> <p>1 information to assess the diminution of value,</p> <p>2 if any.</p> <p>3 Q. Yeah. And assuming all of that to be</p> <p>4 true, it's correct that you didn't attempt to</p> <p>5 provide a formula or describe a methodology at</p> <p>6 which any of those values could be quantified;</p> <p>7 correct?</p> <p>8 A. I do not describe how an economist</p> <p>9 would consider putting a dollar value on loss of</p> <p>10 consumer welfare. It is the concept that is</p> <p>11 underlying my report.</p> <p>12 I described the information that would</p> <p>13 be needed to do so and note that that</p> <p>14 information is individualized and not</p> <p>15 class-wide.</p> <p>16 Q. So, in other words, if a court and/or</p> <p>17 jury were to decide that the proper measure of</p> <p>18 damages in this case is the actual dollars paid</p> <p>19 by both consumers as well as TPPs, and that</p> <p>20 number is \$4.4 billion, you would have no way to</p> <p>21 reduce that by ascribing any value or diminution</p> <p>22 to the value elements that you described for me;</p> <p>23 correct?</p> <p>24 A. I don't think I'm following the</p>	<p style="text-align: right;">Page 73</p> <p>1 I have given my report and testimony, and I --</p> <p>2 my role has typically ended.</p> <p>3 Q. I want you to assume the following,</p> <p>4 and I want you to listen carefully to me.</p> <p>5 I want you to assume you haven't</p> <p>6 testified yet.</p> <p>7 I want you to assume that the result</p> <p>8 of a legal proceeding is that gross damages in</p> <p>9 the amount of \$4 billion have been arrived at</p> <p>10 through testimony other than your own and</p> <p>11 through legal conclusions that the court made,</p> <p>12 and that the gross damages in this hypothetical</p> <p>13 case is \$4 billion, which was derived at by</p> <p>14 simply adding the amount of that consumers paid</p> <p>15 and insurers paid, and the court is now inviting</p> <p>16 you as an expert to tell the court how to</p> <p>17 diminish that sum by the value which you believe</p> <p>18 the consumers or insurers in this case received.</p> <p>19 Tell me the method by which you will</p> <p>20 apprise the court how to diminish the 4 billion</p> <p>21 sum.</p> <p>22 A. In a scenario where the court has</p> <p>23 determined a sum of money, if -- to me, if they</p> <p>24 have determined what damages are, then I have</p>

<p style="text-align: right;">Page 74</p> <p>1 got to say this is outside of my experience to 2 understand what it is that I'm now being asked 3 to do. 4 If a judge were to tell me, I 5 understand, here is all of the spending on the 6 drugs. How do I get from this spending to what 7 are economic damages? 8 Depending on the information that I 9 have available to me, if it is the set of 10 information that I have in my report, I would 11 explain to the judge that individual information 12 is required from consumers to assess the 13 diminution of value in the product that they 14 actually experienced. 15 Q. And you would agree you didn't do that 16 in your report; correct? 17 A. I don't think that is correct. 18 I think exactly what I have done in my 19 report is to tell the court or the judge that 20 individual information is required to assess 21 diminution of value. 22 Q. Did you provide a methodology for 23 arriving at a dollar value assigned to the 24 intangible values you've described?</p>	<p style="text-align: right;">Page 76</p> <p>1 Can we take a minute off -- can we 2 take a minute off the record? We've been 3 going -- I know we had a break, but I would 4 like to take a -- a bio break, if we could. 5 MR. HONIK: Yeah. Okay. I'm in the 6 middle of something. There's one or two 7 questions that would be a more -- 8 MR. GOLDBERG: Okay. Why don't you go 9 ahead. That's fine. Go ahead, Ruben. 10 Q. Dr. Stiroh, did it matter to you in 11 your analysis and in arriving at your opinions 12 whether it is permissible under U.S. law to sell 13 adulterated or misbranded drugs to U.S. 14 consumers and end payers? 15 A. It matters to my opinions. 16 I have an opinion that that fact, if 17 or where true, does not mean that the drugs do 18 not have value to consumers. 19 I have opinions in my report that 20 relate to the fact that the drugs at issue were, 21 in fact, sold and consumed by consumers. 22 Q. If you were told to assume that 23 adulterated drug products cannot be placed into 24 the stream of commerce, would any of your</p>
<p style="text-align: right;">Page 75</p> <p>1 A. I have not laid out a framework in my 2 report for assessing the reduction in consumer 3 welfare, if any. 4 I have described that that cannot be 5 done without information that is individualized. 6 Q. Did you consider whether or not 7 adulterated drugs can be placed into and sold 8 within the U.S. drug supply market, that is, 9 placed into the interstate commerce in the 10 United States? 11 A. I have considered that -- in my 12 report, I have considered that in the context of 13 evaluating Dr. Conti's opinions. 14 I have an example in my report where 15 it is not reasonable from an economic standpoint 16 to assume that a product loses value because it 17 is not FDA approved in the U.S. where it may be 18 FDA approved elsewhere, and that it is not 19 reasonable to assume from an economic standpoint 20 that because it is not FDA approved, it would 21 have zero value to all potential consumers. 22 MR. GOLDBERG: Ruben, could we -- 23 Q. Did it matter to you -- 24 MR. GOLDBERG: Can you hear me?</p>	<p style="text-align: right;">Page 77</p> <p>1 opinions have changed? 2 A. On a going-backward basis for 3 considering the diminution of value, if any, for 4 products that were consumed, that factor does 5 not affect whether consumers obtained value for 6 the product that they consumed, I have 7 considered and described elsewhere in my report 8 a consideration of how to evaluate differences 9 in financial outcomes for consumers if the 10 products had not ever been available in the 11 United States. 12 MR. HONIK: This is a good time to 13 break. 14 Go off the record. 15 THE VIDEOGRAPHER: The time now is 16 12:07 p.m. We are off the record. 17 (A recess was taken from 12:07 to 18 12:15.) 19 THE VIDEOGRAPHER: The time right now 20 is 12:15 p.m. We are back on the record. 21 Q. Dr. Stiroh, are you ready to proceed? 22 A. I am. Thank you. 23 Q. I want to develop just a little kind 24 of -- call it almost a side understanding here</p>

<p style="text-align: right;">Page 78</p> <p>1 by way of a -- an illustration unrelated to this 2 case specifically, but just to understand how 3 you do certain things as an economist in 4 analyzing litigation issues. 5 If you're working on an antitrust 6 case, for example, involving a claim of generic 7 delay -- an antitrust claim of generic delay, 8 would an economist -- or doesn't an economist 9 typically try to assess what impact to the cost 10 of the drugs during the period of delay may or 11 may not have occurred? 12 A. In a generic delay case, an economist 13 may consider potentially whether there was a 14 difference in the cost of the drugs, but also 15 the price of the drugs to which they were sold 16 through various channels of distribution. 17 Q. Right. And I -- look, I don't want to 18 belabor this. I just -- I don't need to be 19 provocative. I just want to get certain 20 understanding about how you go about things as 21 an economist. 22 But the claim in that case is that 23 consumers and/or insurers pay more for the drug 24 than they should have because there was some</p>	<p style="text-align: right;">Page 80</p> <p>1 outcomes would have been had the point of 2 generic entry occurred earlier. 3 Q. Right. When you say "back-casting," 4 you mean creating a but-for world where there is 5 different points of generic entry; right? 6 A. Yes. 7 Q. And all I -- and here is, sort of, the 8 punch line. 9 I just want to understand, where do 10 you collect or get the historic data for 11 pricing? 12 A. In cases that I have worked on, there 13 have been -- has been available data both for 14 scenarios where there are few generic 15 manufacturers and cases where there then has 16 been later in the timeframe generic entry. 17 And from the actual data on actual 18 transactions for the products at issue, it is 19 possible to construct a model to say what if 20 the -- a generic had entered six months earlier? 21 And we see from the pricing pattern 22 what actually happened to prices when the 23 generic did enter, and we consider can that be 24 moved back six months? How did economic</p>
<p style="text-align: right;">Page 79</p> <p>1 collusion or antitrust behavior that caused the 2 delay for generic entry. 3 That's what those cases are about; 4 right? 5 MR. GOLDBERG: Objection to form. 6 Ambiguous. 7 A. There are generic delay cases that I 8 am aware of that have the economic component 9 that I would be familiar with is that the -- the 10 price of the product is higher than it otherwise 11 would be. 12 But for the delay, there could also be 13 a component that the cost is also different. 14 Q. Where do you turn to to understand 15 what the pricing is or was for the drugs in 16 question in that scenario? Where do you turn? 17 A. In cases where I have worked on a 18 generic delay matter, the data that I look at is 19 frequently historic data. 20 Cases that I have been involved in 21 have had a period where there is no generic 22 entry and a period when there is generic entry, 23 and the economic exercise is essentially 24 back-casting from that data to consider what</p>	<p style="text-align: right;">Page 81</p> <p>1 conditions vary in the six-month-earlier period? 2 Are there other factors, such as availability of 3 the active ingredient? Factors such as that. 4 But it's essentially in matters like 5 that that I have worked on. 6 There are cases where we do have 7 representative data to show what happens when 8 there is generic entry and how prices behaved 9 prior to generic entry. 10 Q. Yeah. I understand all that. 11 And do you get the pricing data from 12 IQVIA? 13 A. I have worked with pricing data from 14 IQVIA for matters like that, yes. 15 Q. And you find that reliable data? 16 MR. GOLDBERG: Objection to form. 17 Speculative. Ambiguous. 18 A. It matters as to what it is that I am 19 using it for. 20 The IQVIA data are generally used, in 21 my experience in pharmaceutical matters, because 22 they gather data from a variety of different 23 sources. 24 In matters that I have worked on, it</p>

<p style="text-align: right;">Page 82</p> <p>1 may be that that -- those data are supplemented 2 by information on sales and prices from the 3 manufacturers. 4 But I have used IQVIA data in other 5 matters. 6 Q. So if I heard you correctly, there are 7 two sources for what you described as historic 8 data -- or historical data: Sales and pricing 9 from the actual manufacturer, as well as pricing 10 information from IQVIA; correct? 11 A. I'm not sure what you're asking me. 12 Are you asking me specifically what I 13 have looked at, or you're asking me to tell you 14 what might be available in a generic delay case? 15 Q. I'm asking you if as an economist in 16 doing antitrust cases, you routinely rely on 17 both IQVIA sales data, pricing data, as well as, 18 when available, sales and pricing data from the 19 manufacturer of a particular pharmaceutical drug 20 product. Yes or no? 21 MR. GOLDBERG: Objection to form. 22 Ambiguous. 23 A. In matters that I have been involved 24 in that involved pharmaceutical markets, I have</p>	<p style="text-align: right;">Page 84</p> <p>1 A. I don't think that is correct. 2 I have read the complaint. I have 3 read the information in -- that is listed in my 4 Exhibit 2 to my report. 5 I have reviewed other information on 6 other court filings, but I did not set out to 7 understand all of the theories of harm or 8 liability from a legal standpoint. 9 I have looked at information that is 10 relevant to a consideration of economic loss 11 damages. 12 Q. Did you consider whether or if 13 warranties were breached in this case? 14 A. I did not make an assumption one way 15 or another whether or if warranties were 16 breached in this case. 17 Q. Did you consider what the proper 18 measure of damages would be for a breach of 19 warranty-based claim? 20 MR. GOLDBERG: Objection to form. 21 Calls for a legal opinion. 22 A. I'm not opining and not offering an 23 opinion to the court on what the appropriate 24 measure of damages would be for a breach of</p>
<p style="text-align: right;">Page 83</p> <p>1 relied on IQVIA data. 2 I don't know if I can say that I 3 relied on it in every instance, but I have 4 relied on IQVIA data, and I have relied on 5 information available from the manufacturers. 6 Q. Thank you. 7 Now, before we broke, we spoke a 8 little bit about the impact of the theories of 9 liability in this case to your economic 10 analysis. 11 Do you remember we talked a bit about 12 that? 13 A. I do. 14 Q. And I know you discussed and you 15 listed among your -- the reliance materials the 16 complaint in this case which formed the 17 plaintiffs' allegations. 18 You've looked at the briefing on class 19 certification. 20 You've certainly acquainted yourself 21 with the various theories of liability against 22 not only the manufacturers, but all of the 23 defendant entities in this supply chain; 24 correct?</p>	<p style="text-align: right;">Page 85</p> <p>1 warranty claim. 2 I have considered the economic 3 theories that underlie economic losses and 4 described how I approached that type of 5 analysis. 6 And to the extent that that is 7 relevant to various theories of liability that a 8 court might consider, the court can take my 9 opinion into account. 10 I have not set out to tell the court 11 what theory of damages applies to different 12 theories of harm. 13 Q. I'm a little confused. 14 What do you mean by "underlying 15 theories" in your answer? 16 A. I'm not sure how I used it. 17 Q. Okay. 18 MR. HONIK: Jeff, can I have the 19 answer read back to me, please. 20 (The record was read back.) 21 Q. Dr. Stiroh, what did you mean by 22 "considered economic theories" in that response 23 that the court reporter just read back? 24 A. I had in mind the discussion that is</p>

<p style="text-align: right;">Page 86</p> <p>1 in my report that considers diminution of value 2 being the difference between the price paid and 3 the value received. From an economic 4 standpoint, that is a change in consumer 5 surplus. 6 I have also considered a difference in 7 financial outcomes, and that is the difference 8 in prices paid in a scenario where the products 9 at issue were consumed compared to a scenario 10 where alternative products would have been 11 purchased. 12 Q. Well, is it fair to say that each of 13 the two models that you just described would be 14 measures of damage? 15 MR. GOLDBERG: Objection. Calls for a 16 legal opinion. 17 THE COURT REPORTER: Counsel, could 18 you repeat that question? I didn't hear it 19 clearly. This is Jeff. 20 Q. Did you hear it, Dr. Stiroh? 21 A. I believe that I did, yes. 22 Q. Okay. For the benefit of the court 23 reporter, let me try to restate or rephrase it. 24 You described, one -- I'll call it a</p>	<p style="text-align: right;">Page 88</p> <p>1 Q. Yes, ma'am. 2 A. I think you use "cost" differently 3 from how I use it, and I'm concerned there could 4 be some confusion. 5 I -- my model, where I would consider 6 differences in financial outcomes from the 7 standpoint of a consumer, I consider the 8 financial outlay, the difference in their 9 financial position purchasing the products at 10 issue and an alternative product. 11 For a -- somebody further upstream, 12 then it may be relevant to consider the 13 difference in both the prices paid and the costs 14 of the -- acquiring the product. 15 Q. Yeah. So I completely understand. 16 Let me give you an illustration of 17 what I understand you mean by the measure of 18 damages we're referring to as financial outcome. 19 If someone pays \$10 for a drug and you 20 now want to compare the cost of getting an 21 alternative drug, if that alternative drug is 22 \$12, there's no economic loss, because the 23 alternative cost exceeds the paid price; 24 correct, in that hypothetical? Right?</p>
<p style="text-align: right;">Page 87</p> <p>1 model or a measure that you referred to as 2 "diminution of value." 3 Do you remember that? 4 A. Yes. 5 Q. And then you described what I 6 understood, and I wrote down in shorthand, 7 another measure or formula that you referred to 8 as "financial outcome." 9 Do you remember that? 10 A. I do. 11 Q. The second of those two, the 12 financial -- could we refer to it, just for ease 13 of reference in our talk here, to the second 14 model or measure as financial outcome and the 15 first one diminution? 16 Would that be okay with you? 17 A. Yes. 18 Q. So if we focus on financial outcome, 19 if I listen carefully, the formula for 20 determining damages under that approach would be 21 prices paid and compare it to alternative 22 product cost; correct? 23 A. You are describing for me what I said 24 is a model comparing financial outcomes?</p>	<p style="text-align: right;">Page 89</p> <p>1 A. No. In that hypothetical, there is no 2 financial loss to the consumers. 3 I have defined economic loss in my 4 report as a difference between the price paid 5 and the value received. 6 Q. Okay. But I don't want to leave this 7 area until I've understood the two measures that 8 you've outlined for me. 9 And the one we're going to focus on 10 now is what we referred to -- I referred to, and 11 you agreed to accept -- as financial outcome. 12 Can you give me an example using 13 specific drugs and costs and tell me how 14 financial outcome is a measure? 15 A. If there were a consumer that was 16 taking Valsartan, and in the absence of supply 17 of the Valsartan that they consumed they would 18 have switched to Irbesartan, the difference in 19 financial outcomes for them depends on whether 20 they are a cash consumer and pay a retail price 21 for two products, because the retail prices are 22 different, or whether they are insured, and then 23 it depends on their insurance plan and what the 24 co-pay or co-insurance amount is for differences</p>

<p style="text-align: right;">Page 90</p> <p>1 for the -- the two products.</p> <p>2 The exercise is to consider what were</p> <p>3 the financial outlays for the Valsartan that</p> <p>4 they purchased and what the financial outlays</p> <p>5 would have been had they consumed a different</p> <p>6 blood pressure medication.</p> <p>7 Q. That's correct. So if the financial</p> <p>8 outlay would have been \$10 for the Valsartan and</p> <p>9 the replacement drug is \$12, there's no</p> <p>10 financial outlay or loss to that consumer,</p> <p>11 right; in the simplest terms; right?</p> <p>12 A. If the financial outlay would have</p> <p>13 been the same, that is correct, there is no</p> <p>14 difference in the financial outcomes for the</p> <p>15 consumer.</p> <p>16 Q. I actually completely misspoke. I</p> <p>17 misspoke.</p> <p>18 If the replacement drug was actually</p> <p>19 \$12, or \$2 more, their loss is \$2, in my</p> <p>20 hypothetical; correct?</p> <p>21 A. No. I think you have assumed that the</p> <p>22 financial outlay for the replacement drug is</p> <p>23 higher, which is a reasonable assumption,</p> <p>24 because I think the replacement drugs often did</p>	<p style="text-align: right;">Page 92</p> <p>1 they go for, pay for a month's supply of</p> <p>2 Valsartan and a month's supply of the</p> <p>3 replacement product, the financial loss is \$2 in</p> <p>4 your scenario.</p> <p>5 Q. And turning to the diminution model,</p> <p>6 which you said was price minus the value</p> <p>7 received, if the price of the drug was \$10 and</p> <p>8 the value you're ascribing is control of one's</p> <p>9 blood pressure, what would the deduction be?</p> <p>10 A. The -- sorry. The scenario here is to</p> <p>11 consider for a consumer the diminution of value</p> <p>12 from the Valsartan at issue?</p> <p>13 Q. That's right.</p> <p>14 A. Yes. Then the consideration for that</p> <p>15 consumer is how they value the -- or would price</p> <p>16 the increased risk of their consumption of</p> <p>17 Valsartan, if any, because of the presence of</p> <p>18 alternatives, and whether that has a change to</p> <p>19 their risk profile of eventually contracting a</p> <p>20 disease that they wouldn't, in the absence of</p> <p>21 the impurities at issue.</p> <p>22 And the diminution of value, their</p> <p>23 internal intrinsic valuation of the product</p> <p>24 would depend on things such as how much they had</p>
<p style="text-align: right;">Page 91</p> <p>1 have a higher price.</p> <p>2 But for that consumer, they did not</p> <p>3 suffer a financial loss from taking the</p> <p>4 Valsartan at issue, because their financial</p> <p>5 outlays would have been higher in the absence of</p> <p>6 the supply of the Valsartan product that they</p> <p>7 consumed.</p> <p>8 Q. What if the replacement drug was less</p> <p>9 expensive than the \$10 Valsartan cost?</p> <p>10 A. In instances for class members who</p> <p>11 would have switched to a replacement drug and</p> <p>12 had a lower financial outlay, their financial</p> <p>13 losses are calculated as the difference in the</p> <p>14 financial outlay consuming Valsartan and the</p> <p>15 financial outlay that they would have had with a</p> <p>16 different medication.</p> <p>17 Q. So if in my hypothetical it was \$10</p> <p>18 for the Valsartan and \$8 for the replacement or</p> <p>19 alternative, what's the loss for that consumer</p> <p>20 in your model?</p> <p>21 A. The financial loss to the consumer in</p> <p>22 that model would be \$2.</p> <p>23 If it is assuming equivalence of the</p> <p>24 product that they're purchasing, if that is what</p>	<p style="text-align: right;">Page 93</p> <p>1 to consume, over what timeframe, the degree of</p> <p>2 impurities, if any, in the product that they</p> <p>3 consumed, their ability to manage their blood</p> <p>4 pressure with Valsartan compared to what the</p> <p>5 alternative products might be, what side effects</p> <p>6 of alternatives might be that made Valsartan be</p> <p>7 the product of choice for that consumer, and, my</p> <p>8 understanding, things like their weight and</p> <p>9 health history.</p> <p>10 Q. Dr. Stiroh, I confess, I'm completely</p> <p>11 confused by your answer.</p> <p>12 What I want to understand before</p> <p>13 moving on is how your diminution model works.</p> <p>14 And I want you to assume that a</p> <p>15 particular consumer of a VCD has paid \$10 for</p> <p>16 his or her prescription.</p> <p>17 And the question in court and for you</p> <p>18 as an economist is, what, if any, financial loss</p> <p>19 did that individual suffer by accepting as true</p> <p>20 that there's some impurity or contamination to</p> <p>21 that product?</p> <p>22 What would you look at in the</p> <p>23 diminution model, assuming the consumer paid</p> <p>24 \$10?</p>

<p style="text-align: right;">Page 94</p> <p>1 Tell me what you would do step by</p> <p>2 step.</p> <p>3 MR. GOLDBERG: Objection. Asked and</p> <p>4 answered.</p> <p>5 A. I think in your question you added</p> <p>6 financial loss into how I would approach the</p> <p>7 diminution.</p> <p>8 I have described them in my report as</p> <p>9 two separate pieces.</p> <p>10 The financial loss is what comes out</p> <p>11 of your pocket.</p> <p>12 The diminution of value starts with an</p> <p>13 economic framework where the price that a person</p> <p>14 pays for a product, the fact that they have gone</p> <p>15 and paid that price indicates to an economist</p> <p>16 that they value the product at least as much as</p> <p>17 the price paid.</p> <p>18 If there is additional information</p> <p>19 that comes to light that changes their</p> <p>20 understanding of a product that they received,</p> <p>21 so that they understand that they received a</p> <p>22 different product than they believed they were</p> <p>23 purchasing, it is possible that their value for</p> <p>24 that product would have been diminished.</p>	<p style="text-align: right;">Page 96</p> <p>1 explain them, then I'll consider them.</p> <p>2 Q. Yes, I can tell you.</p> <p>3 I wrote down that you said one way to</p> <p>4 look at value is, quote, financial loss is what</p> <p>5 comes out of your pocket.</p> <p>6 Remember you told me that?</p> <p>7 A. I did tell you that.</p> <p>8 My recollection when I said that was</p> <p>9 because the question that you had asked me had</p> <p>10 diminution of value and financial loss.</p> <p>11 And in the prior questions, we had</p> <p>12 separated those two topics, and I was clarifying</p> <p>13 for you the financial loss discussion has to do</p> <p>14 with the money that comes out of your pocket.</p> <p>15 The diminution of value discussion has</p> <p>16 to do with the intrinsic value of a product to a</p> <p>17 consumer who purchases it.</p> <p>18 Q. That's right. Financial loss is</p> <p>19 defined by you as what comes out of your pocket,</p> <p>20 and diminution in value is what you paid less</p> <p>21 consumer welfare; right, loss of consumer</p> <p>22 welfare?</p> <p>23 Is that what you said?</p> <p>24 A. Yes.</p>
<p style="text-align: right;">Page 95</p> <p>1 As economists, we think of that as a</p> <p>2 loss of consumer surplus. I think I used the</p> <p>3 phrase "consumer welfare." I mean them</p> <p>4 equivalently.</p> <p>5 The measures of consumer welfare would</p> <p>6 depend on what the loss of intrinsic value to a</p> <p>7 customer is based on the new information about</p> <p>8 the product that they consumed.</p> <p>9 That diminution is going to depend on</p> <p>10 factors that are specific to an individual, such</p> <p>11 as the risk of consuming it, the information</p> <p>12 that they may receive from their doctor, their</p> <p>13 health histories, their own aversion to risk, or</p> <p>14 their willingness to accept risk because of the</p> <p>15 attributes of the product that they feel they</p> <p>16 cannot get elsewhere.</p> <p>17 Q. That is extremely helpful, because if</p> <p>18 I've understood you correctly, there are</p> <p>19 actually two definitions of "value," according</p> <p>20 to you in your last answer; correct?</p> <p>21 MR. GOLDBERG: Objection to form.</p> <p>22 Ambiguous. Mischaracterizes the testimony.</p> <p>23 A. I don't know what you have in mind as</p> <p>24 my two definitions of "value." If you could</p>	<p style="text-align: right;">Page 97</p> <p>1 Q. And so if we focus only on what you've</p> <p>2 now defined for all of us as financial loss,</p> <p>3 namely, what comes out of your pocket, that --</p> <p>4 that's one measure of damage; right?</p> <p>5 MR. GOLDBERG: Objection to form.</p> <p>6 Calls for a legal opinion.</p> <p>7 A. Financial losses have been used as a</p> <p>8 measure of damages in economic matters in which</p> <p>9 I have been engaged.</p> <p>10 Diminution of value considers other</p> <p>11 factors, not just the market prices of products.</p> <p>12 Q. Tell me as succinctly as you can how</p> <p>13 you yourself have used and measured financial</p> <p>14 loss in matters in which you've been engaged as</p> <p>15 an expert economist.</p> <p>16 A. I have considered -- sorry. Just to</p> <p>17 make sure I'm answering it correctly, I'm just</p> <p>18 going to ask that the question be read back</p> <p>19 again.</p> <p>20 Q. Sure.</p> <p>21 (The record was read back.)</p> <p>22 A. All right. I have measured financial</p> <p>23 loss for a class of franchisees who were the --</p> <p>24 alleged wrongdoing was that they did not have</p>

<p style="text-align: right;">Page 98</p> <p>1 available to them multiple source of supply for 2 products that they needed to run their 3 franchises. 4 And I measured that using a regression 5 analysis where I compared the prices for the 6 necessary inputs where there were multiple 7 sources of supply, with necessary inputs where 8 there were few sources of supply to estimate 9 what happens to prices when there are available 10 additional sources of supply. 11 And I used that to estimate what the 12 difference in profits would have been for the 13 franchisees had there been additional sources of 14 supply for a number of necessary products. 15 I have performed -- 16 Q. Let me -- I'm sorry. I didn't mean to 17 cut you off. Please continue. 18 A. I understood that your question to ask 19 me how I have done this, but -- how I have 20 considered financial losses, and I can take you 21 through the ones that I remember. 22 Q. Let me clarify. 23 As a way of explaining to me and to 24 others listening to you, as an economist, what</p>	<p style="text-align: right;">Page 100</p> <p>1 certain inputs, in addition to, or in the 2 alternative, where the conduct at issue affects 3 the prices of products paid, I have worked on 4 matters where the conduct at issue affects the 5 availability of alternative products. 6 Basically, economics has to do with 7 the interaction of various economic variables, 8 and if something changes in the supply chain, 9 there may be other economic implications for 10 other variables. 11 And the economist's role would be to 12 consider those implications and arrive at a 13 comparison of the financial situation as is and 14 the financial situation as it would have been 15 under different circumstances. 16 Q. I totally understand that answer. 17 What you're conveying is that you 18 start by looking, as you put it, at economic 19 circumstances, which is often the price in 20 question that was paid; right? 21 That's where you started; correct? 22 A. That is often a starting place, 23 correct. 24 Q. That's right. It's often the starting</p>
<p style="text-align: right;">Page 99</p> <p>1 the formula or model is for financial loss. I 2 understand you've given a very concrete example. 3 Can you give me a somewhat more 4 generic -- generic or general description of how 5 financial loss as an economist is arrived at, 6 that is, how you figure out someone or some 7 entity's loss coming out of their pocket? 8 How do you determine that? 9 A. I consider -- 10 MR. GOLDBERG: Objection. Ambiguous. 11 A. -- the economic circumstances of the 12 entity in the world as it is, and that may 13 include the prices paid, or for an entity 14 further up the distribution chain, the prices 15 paid in the costs -- or the prices received and 16 the costs paid, and I consider what the economic 17 variables would be in the absence of some 18 conduct that is challenged as being wrongful. 19 And that analysis depends on what 20 conduct is challenged to be wrongful and the way 21 that that conduct would interact with economic 22 variables. 23 I have worked on matters where the 24 conduct at issue would affect the cost of</p>	<p style="text-align: right;">Page 101</p> <p>1 place. 2 And then if I've understood you, what 3 you look at is the alleged conduct that alters 4 that construct, the liability, and you look at 5 and consider a but-for world of sorts in which 6 that conduct did not occur, and then you try to 7 figure out that economic variable in its absence 8 what impact to price occurs; right? 9 A. I don't -- 10 MR. GOLDBERG: Objection. Ambiguous. 11 THE WITNESS: Sorry. 12 A. I don't think so precisely. 13 You put the word "liability," when -- 14 in your restatement, and that's not something 15 that I considered. 16 I consider the economic implications 17 of conduct and not liability because -- as I 18 understand it as a legal matter. 19 Q. I take your point. And you're right, 20 I speak as a lawyer. 21 And, really, what I meant to say and 22 should have said is "conduct." That's the word 23 you used to describe the shift or the point of 24 comparison, economically speaking, between the</p>

<p style="text-align: right;">Page 102</p> <p>1 starting point, which is the price paid, and 2 this sort of but-for economic scenario that was 3 caused by some conduct; correct? 4 MR. GOLDBERG: Objection. 5 Mischaracterizes. 6 A. I think at a high level, that is 7 correct. 8 I consider the economic scenario that 9 would have unfolded absent some type of conduct 10 in a consideration of financial loss damages 11 where the financial losses are differences in 12 economic outcomes. 13 Q. And reasonable economic minds can 14 disagree about the components of that model or 15 measure; isn't that true? 16 MR. GOLDBERG: Objection to form. 17 Ambiguous. 18 A. I don't know what you have in mind 19 about what the reasonable minds would disagree 20 on with respect to the components of that 21 measure. 22 I have been involved in matters where 23 there was disagreement over the appropriate 24 interest rate, what the cost implications of</p>	<p style="text-align: right;">Page 104</p> <p>1 these VCDs during the class period; correct? 2 A. Did you say there's no ambiguity in my 3 mind? 4 Q. That's right. 5 A. I'm not aware of a dispute on those 6 market facts. If there is one, it's something 7 that I'm not aware of. 8 I understand that to be in the class, 9 a consumer had to have paid some amount for a -- 10 for the Valsartan that they consumed. 11 Q. That's right. I mean, the 12 prescription records are so abundantly detailed, 13 that we know exactly what consumers contributed 14 and we know how much insurers paid. 15 That's not in dispute in this case; 16 right? 17 A. I disagree with that. 18 MR. GOLDBERG: Objection to form. 19 A. One of the issues that matters at the 20 class certification stage is whether you can 21 tell whether a class member has -- what amount 22 they have paid. And I think you need to do -- 23 you need individual information from class 24 members on that.</p>
<p style="text-align: right;">Page 103</p> <p>1 certain conduct was, what available alternatives 2 might have been. 3 I don't know if I'm agreeing with you 4 or disagreeing with you at this point. 5 Q. No. I -- I kind of get what you're 6 doing. 7 So reasonable economic minds could 8 disagree about the starting pricing, right, that 9 you're starting with the -- as you put it, 10 economic circumstances, you -- one could 11 disagree about what the starting price is; 12 right? 13 A. I would have to think of a situation, 14 and I don't -- only because when I said starting 15 price and agreement with you, I had in mind 16 actual prices as they are. Those would be 17 market facts. Those -- that would be 18 information in the record, and I don't see a 19 dispute over that. 20 Q. Okay. So let's start with that. 21 That's a good starting place. 22 There's no dispute in your mind that 23 the market fact, the market reality, is that 24 consumers and insurers paid what they paid for</p>	<p style="text-align: right;">Page 105</p> <p>1 I think that what you are saying is 2 some amount in aggregate. And even there, there 3 could be dispute over whether that is the amount 4 paid or whether it fails to include things like 5 discounts or rebates that were given at a time 6 and collected in a different database and cannot 7 be accurately tied back to the initial purchase. 8 Q. Do you -- do you dispute anywhere in 9 your report what the economic circumstances or 10 prices paid were by the two economic classes? 11 A. I do not dispute that there were 12 prices paid by the two purported classes. 13 It is my opinion that to assess on a 14 class-member-by-class-member basis what the 15 damages incurred by any individual class member, 16 you would need information on the price that 17 that actual class member paid. And that 18 information is not widely available. It is -- 19 to my mind, we only -- 20 Q. Weren't you -- 21 MR. GOLDBERG: Hang on. Wait. Let 22 the witness answer the question. 23 A. I understand that there has been some 24 data provided only by three plaintiffs, and one</p>

<p style="text-align: right;">Page 106</p> <p>1 plaintiff had, I think, some aggregated data, 2 but I don't think that there exists in this case 3 class-member-by-class-member expenditures on the 4 products at issue. 5 Q. Class-member-by-class-member 6 expenditures? Is that what you said? 7 A. It is. 8 Q. Is it your opinion that 9 class-member-by-class-member expenditure needs 10 to be demonstrated in order to certify a class? 11 Is that your opinion? 12 MR. GOLDBERG: Objection to form. 13 Calls for a legal opinion. 14 A. My understanding as an economist is 15 that one of the things that a court would 16 consider in determining to certify a class is 17 whether the class members have been harmed. 18 And when I use "harm," I use it in an 19 economic sense, by the conduct at issue, where 20 the measure of harm being considered is 21 diminution of value. 22 And that is the difference between the 23 price paid and the value received, you need to 24 have information on the price paid, and then you</p>	<p style="text-align: right;">Page 108</p> <p>1 measure of damages that you described to me, 2 that you and I have been referring to as 3 "financial loss," which begins by looking at 4 actual prices. 5 Isn't that what you told me? 6 MR. GOLDBERG: Objection to form. 7 Mischaracterizes the record. 8 A. I'm not sure what you're asking me. 9 I think you're -- 10 Q. I'm asking you if it is true that you 11 told me under oath that in looking at the 12 financial loss model, which is the loss that 13 comes out of your pocket, one begins by looking 14 at, as you put it, economic circumstances, which 15 is usually the actual price paid for something. 16 Isn't that the starting point? 17 MR. GOLDBERG: Objection to form. 18 Mischaracterizes the testimony. 19 A. For financial losses, you compare the 20 actual economic circumstances of a class member 21 with the economic circumstances -- the financial 22 economic circumstances they would have 23 experienced under some alternative. 24 And so an input, whether it is the</p>
<p style="text-align: right;">Page 107</p> <p>1 also need information that would allow you to 2 assess the value received. 3 Both of those require individual 4 information that has not been provided, or I'm 5 not aware of, on a class-member-by-class-member 6 basis. 7 Q. Dr. Stiroh, we're not talking about 8 your diminution model; we're talking about your 9 financial outcome or financial loss model. 10 Do you remember that? 11 MR. GOLDBERG: Objection -- 12 Q. That's what I want to stick with. 13 Can we do that? 14 MR. GOLDBERG: Objection to form. 15 Mischaracterizes the record. 16 A. Within the financial model, the 17 information that is not currently available on a 18 class-member-by-class-member basis is still the 19 amount that they actually paid for both models. 20 One of the inputs is the actual 21 expenditures, and we don't have that information 22 on a class-member-by-class-member basis. 23 Q. Ma'am, I want to direct your attention 24 to one thing and one thing only, and that is the</p>	<p style="text-align: right;">Page 109</p> <p>1 first one or a different -- or something 2 considered later on is what they actually paid 3 for the product at issue. 4 Q. That's right. What they actually paid 5 for the product. Let's just stop there. 6 The question I next have is: In 7 calculating the actual price paid, isn't it true 8 that as an economist, you can take an aggregate 9 of the prices paid for the products in question? 10 Yes or no? 11 MR. GOLDBERG: Objection to form. 12 Ambiguous. 13 A. It depends on what your purpose is. 14 If your purpose is to assess the 15 aggregate expenditures, you can use an 16 aggregate. 17 If your purpose is to assess whether 18 you can -- whether class members have been 19 financially affected by the conduct under 20 consideration, you need to evaluate the 21 expenditures on a class-member-by-class-member 22 basis. 23 Q. And then the next step would be, as 24 you described it, to look at the alternative</p>

<p style="text-align: right;">Page 110</p> <p>1 circumstance and assign a value to that; 2 correct? 3 A. What do you mean by "assign a value to 4 that"? 5 Q. Well, you tell me. We're looking at 6 your financial loss model. We've now 7 established the pricing and the way that you've 8 described. 9 How would you then arrive at a dollar 10 value for this alternative circumstance in order 11 to determine the loss? 12 A. In a situation such as this one where 13 class members can choose to take different 14 actions -- 15 Q. I'm not asking you about this one, 16 Doctor, respectfully. I'm not asking you about 17 VCDs. 18 I'm asking you about this measure, 19 this model that we're talking about generally in 20 economics. 21 You've established there's a financial 22 loss model, which is defined as what comes out 23 of your pocket. The starting place is actual 24 economic circumstances, typically prices paid.</p>	<p style="text-align: right;">Page 112</p> <p>1 alternative course of conduct. 2 Q. So the two terms that I wrote down 3 that you employed was "the actual world," and 4 then you compare it to the "alternative course 5 of conduct world." 6 Did I get that right? 7 A. Yes. 8 Q. And you used the -- the expression 9 "range of alternative circumstances," I think to 10 imply that there are sometimes multiple ways to 11 look at the alternative course of conduct world; 12 correct? 13 MR. GOLDBERG: Objection to form. 14 Mischaracterizes testimony. 15 A. There may be multiple ways to look at 16 the alternative course of conduct world. 17 There may also be alternatives 18 available to purported class members for any 19 particular characterization of the alternative 20 course of conduct world. 21 And in my answer, I may have used the 22 same words to talk about two different things, 23 but there are two points of variation: 24 One, what does the overall alternative</p>
<p style="text-align: right;">Page 111</p> <p>1 You've established that. 2 You've now told me that you -- the 3 next step in this formula that you apply, 4 economically speaking, is to determine the 5 alternative; in other words, the economic 6 variable in the absence of whatever conduct is 7 that changed the world. 8 And I'm asking you, how do you arrive 9 at a dollar value for that to deduct it from the 10 actual price paid? 11 MR. GOLDBERG: Objection to form. 12 Mischaracterizes the testimony. Asked and 13 answered. 14 A. In a general sense, you would consider 15 what the range of alternatives are that are 16 available in the absence of certain conduct, 17 whether there is information that guides which 18 of the alternatives class member might take up, 19 what the costs are of those alternatives, 20 whether there are any relevant market factors to 21 be taken into account, and assess the 22 differences between the financial situation of 23 the -- call it the actual world and the 24 financial situation of a class member under some</p>	<p style="text-align: right;">Page 113</p> <p>1 course of conduct world look like, and then 2 within any one of those, what do consumers do? 3 Q. What do you mean, "what do consumers 4 do," in that sentence? 5 A. With respect to this case, one of the 6 things that consumers might do is choose a 7 different medication in consultation with their 8 doctor to manage their blood pressure. 9 And so the economic circumstances, 10 choosing a different medication, depend on the 11 medication that they choose. 12 Q. And so you would ascribe a cost to 13 that alternative medicine in that scenario and 14 deduct that from the actual cost that you start 15 with; is that right, in that measure? 16 A. From the standpoint of a consumer, I 17 would consider the price that they paid for the 18 medication that they are on and the price that 19 they would have paid for an alternative 20 medication, and the alternative medication can 21 vary class member by class member. 22 Q. And to go back to an example that you 23 and I spoke about and you confirmed, if the 24 actual price was 10 and the alternative price</p>

<p style="text-align: right;">Page 114</p> <p>1 was 8, you told me the loss is 2; right?</p> <p>2 That would be an example of what we</p> <p>3 just described; right?</p> <p>4 MR. GOLDBERG: Objection to form.</p> <p>5 A. The financial loss for a class member</p> <p>6 who paid 8 -- \$10 and would have paid a co-pay</p> <p>7 of \$8 would be 2.</p> <p>8 Q. And if we had an alternative course</p> <p>9 of --</p> <p>10 A. I'm sorry. I said that back -- I</p> <p>11 apologize. I said that backwards. And so the</p> <p>12 answer will not make sense.</p> <p>13 The other way around. If they would</p> <p>14 have paid 8 and would have paid 10 -- no. I</p> <p>15 forget now which way you asked me.</p> <p>16 The difference in financial outlays</p> <p>17 between what they did pay and what they would</p> <p>18 have paid is the measure of financial losses.</p> <p>19 Q. Dr. Stiroh, here's where I end up.</p> <p>20 If the alternate course of conduct is</p> <p>21 subject to various alternative circumstances,</p> <p>22 aren't you telling me that economically, there</p> <p>23 are multiple ways in certain circumstances to</p> <p>24 look at what you're comparing between the actual</p>	<p style="text-align: right;">Page 116</p> <p>1 A. I'm not sure what you mean by that,</p> <p>2 and it may be that I am focused more on this</p> <p>3 case and this framework than in a general sense.</p> <p>4 In this case, the frame -- the</p> <p>5 circumstances that we are considering changing</p> <p>6 is that a consumer chooses a different product.</p> <p>7 The -- depending on the product chosen</p> <p>8 and the insurance plan, if any, for the</p> <p>9 consumer, the amount they pay may differ. A</p> <p>10 different consumer for the same product may pay</p> <p>11 a different price, and a different consumer may</p> <p>12 choose a different product and also pay a</p> <p>13 different price, and all of that would have to</p> <p>14 be considered.</p> <p>15 Q. Dr. Stiroh, from an economic</p> <p>16 standpoint, you acknowledge and understand that</p> <p>17 what Dr. Conti did was a financial loss</p> <p>18 analysis; correct?</p> <p>19 A. In my view, she has done neither a</p> <p>20 diminution of value or a financial loss analysis</p> <p>21 that is consistent with economic principles.</p> <p>22 Q. Yeah. I know that's your conclusion,</p> <p>23 and I know you disagree with her in every</p> <p>24 respect.</p>
<p style="text-align: right;">Page 115</p> <p>1 and this alternate circumstance world?</p> <p>2 It can vary; correct?</p> <p>3 MR. GOLDBERG: Objection. Ambiguous.</p> <p>4 A. The choices that consumers make can</p> <p>5 vary consumer by consumer.</p> <p>6 For an individual --</p> <p>7 Q. I haven't asked you that --</p> <p>8 MR. GOLDBERG: Counsel, don't</p> <p>9 interrupt -- Counsel, don't interrupt the</p> <p>10 witness.</p> <p>11 A. My answer was that the choices that</p> <p>12 consumers make can vary consumer to consumer.</p> <p>13 Q. Yeah. I'm asking a question about</p> <p>14 economics and about economists and models that</p> <p>15 they use.</p> <p>16 And the question I'm posing to you is,</p> <p>17 when you look at the range of alternative</p> <p>18 circumstances, figuring out if it's \$8 or \$9 or</p> <p>19 \$15 to compare to the starting place, which you</p> <p>20 said is the actual price, I'm just asking, that</p> <p>21 can vary depending upon how you look at it;</p> <p>22 correct?</p> <p>23 MR. GOLDBERG: Objection. Ambiguous.</p> <p>24 Asked and answered.</p>	<p style="text-align: right;">Page 117</p> <p>1 But based on what you've now told us</p> <p>2 under oath, she took the actual prices paid by</p> <p>3 consumers and insurers and compared it or</p> <p>4 deducted it from the alternative circumstance.</p> <p>5 And the alternative circumstance in</p> <p>6 Dr. Conti's economic model is that those drugs</p> <p>7 should have never been in the supply chain,</p> <p>8 which means they have a zero value.</p> <p>9 At the minimum, disagreeing as I know</p> <p>10 you do, you understand that that's what she did;</p> <p>11 correct?</p> <p>12 A. I understand that she assumed that all</p> <p>13 of the drugs at issue were worthless, and I</p> <p>14 disagree with her on that.</p> <p>15 She did not do a financial loss model</p> <p>16 because she did not consider in any</p> <p>17 circumstances the financial circumstances of</p> <p>18 consumers if they had consumed a different</p> <p>19 product.</p> <p>20 Q. That's right. Your complaint here is</p> <p>21 that there isn't an offset for a replacement or</p> <p>22 an alternative drug; correct?</p> <p>23 A. For the financial loss model, there</p> <p>24 needs to be a consideration of what consumers</p>

<p style="text-align: right;">Page 118</p> <p>1 would have done in the absence of supply for the 2 Valsartan at issue. 3 Without that consideration there -- it 4 is an incomplete model. It is not consistent 5 with economic theory. 6 Q. Understood. So if we take Dr. Conti's 7 model and fix it in the way you say it needs to 8 be fixed, we'll use this example. 9 The actual price for the drug is \$10. 10 She believes the comparative price in the 11 alternative circle is zero. That means you have 12 net 10. And you have now told us that you now 13 have to take an alternative cost and factor that 14 in. 15 And so if the alternative cost is 8, 16 the person has a \$2 loss; right? 17 A. I'm not sure what you're asking me to 18 agree with in that sentence. 19 You had statements about what 20 Dr. Conti has done or hasn't done, and then 21 something else that needs to be added. 22 In my view, her approach to financial 23 losses is incomplete, because she does not 24 consider what consumers would have purchased in</p>	<p style="text-align: right;">Page 120</p> <p>1 Valsartan-containing drugs. 2 Q. If you were instructed by the court as 3 a matter of law that these contaminated drugs 4 were legally worthless, would you accept that? 5 A. I don't know what that means. 6 I have training and experience as an 7 economist. And as an economist, my opinion is 8 that it is not appropriate to say that they are 9 worthless. 10 If there is a legal opinion and that 11 has legal meaning, then I'm not sure the court 12 needs me. 13 My opinions and my -- the report that 14 I have written give an economic opinion and an 15 economic assessment of the issues involved in 16 assessing class-wide damages from the conduct at 17 issue in this case. 18 Q. Dr. Stiroh, I'm at a loss to 19 understand why you say the court wouldn't need 20 you if the court determined as a matter of law 21 that these contaminated drugs were worthless. 22 The court would still need an 23 economist like you or Dr. Conti to count up the 24 losses.</p>
<p style="text-align: right;">Page 119</p> <p>1 the absence of supply of the 2 Valsartan-containing drugs at issue. 3 Q. You really have two principal 4 objections to what Dr. Conti has done. 5 Objection Number 1 is that she has 6 ascribed zero value or worthlessness to the 7 contaminated drug, and in the model you and I 8 have now been speaking about for the last 9 half-hour she has failed to factor in the actual 10 cost of an alternative drug; right? 11 MR. GOLDBERG: What is the question? 12 A. Those are among the points that I 13 disagree with Dr. Conti's opinion. 14 I disagree that it is appropriate from 15 an economic standpoint to assume the products 16 consumed are worthless. 17 And I disagree that she has put 18 forward a valid damage model because she neither 19 considers the diminution of value to the 20 products -- to the consumers based on the 21 products that they consumed, nor does she 22 consider a financial differences model, which 23 would require considering what patients would 24 have done in the alternative to consuming</p>	<p style="text-align: right;">Page 121</p> <p>1 Don't you agree? 2 MR. GOLDBERG: Objection to form. 3 A. I guess I don't know what the court 4 needs and don't mean to be opining on what the 5 court needs. 6 I have been asked to give my opinions 7 as an economist on certain topics related to 8 economic loss damages and other models of 9 economic damage assessment, and I have done 10 that, and I don't have an opinion on what the 11 court requires. 12 Q. I haven't asked you that. 13 What I have done is what I'm permitted 14 to do, and that is to direct you to accept the 15 hypothetical. 16 And the hypothetical I'm asking you to 17 accept for our -- purposes of discussion is that 18 the drugs are economically worthless as a matter 19 of law, and, in turn, economics, law imposing 20 its will on economics. 21 Under that circumstance, could you, 22 number 1, accept that, and then calculate 23 damages? 24 MR. GOLDBERG: Objection to form.</p>

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1 Calls for a legal opinion. Ambiguous.
 2 Speculation.
 3 A. It is outside my experience for how I
 4 as an economist have a role in various cases
 5 where there are allegations of wrongdoing and an
 6 assessment of harm.
 7 Where I have participated in cases and
 8 assessed damages, I have done my own damage
 9 calculation by applying economic principles.
 10 There is frequently an economist or an
 11 accountant or somebody on the opposing side that
 12 may do an alternative or different measure of
 13 damages.
 14 The -- in my experience, those models
 15 are presented to the court and the court reaches
 16 opinions.
 17 Q. Well, you're confirming that you would
 18 be incapable of accepting as a matter of fact in
 19 your analysis that the comparative in the
 20 alternative circumstance is zero?
 21 You would be unable to accept that and
 22 work with that value; correct?
 23 MR. GOLDBERG: Objection to form.
 24 Mischaracterize the testimony.

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1 A. In my opinion, that is not a measure
 2 of value, and my opinions would be based, as
 3 they are in this case, on what an economist
 4 considers in assessing value.
 5 Q. Doctor, take the next exhibit in your
 6 pile that we sent you there.
 7 MR. GOLDBERG: Ruben --
 8 Q. I believe it's --
 9 MR. GOLDBERG: -- if this is -- you
 10 know --
 11 MR. HONIK: Yes.
 12 MR. GOLDBERG: We said we were going
 13 to take a lunch break. We have been back
 14 on for about an hour.
 15 Is this a good time, or are you still
 16 in this line of questioning?
 17 MR. HONIK: No. I'm still in this
 18 line of questioning.
 19 Q. I would like you to take out, at Tab
 20 Number 6, that document, please.
 21 THE COURT REPORTER: Counsel, this is
 22 the court reporter. I take it you want me
 23 to put exhibit stickers on these as they're
 24 produced?

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1 MR. HONIK: That would be great.
 2 We're going to call this one Stiroh 2,
 3 Exhibit 2.
 4 MR. GOLDBERG: Ruben, do you have a
 5 tile for this document? I just want to
 6 make sure I've got the right one.
 7 MR. HONIK: It's Judge Kugler's Motion
 8 to Dismiss Opinion 3: Warranty Claims.
 9 MR. GOLDBERG: Then I don't have the
 10 right thing.
 11 MR. HONIK: Should be attached.
 12 (MTD Opinion 3: Warranty Claims was
 13 marked Stiroh Exhibit 2 for identification,
 14 as of this date.)
 15 Q. Do you have it?
 16 A. I have this.
 17 Q. Okay. I'm not able to see that.
 18 Can you verify that you're holding the
 19 caption of this case, Judge Kugler's Motion to
 20 Dismiss Opinion 3: Warranty Claims?
 21 A. I do. I have it.
 22 Q. Okay. Have you ever seen Exhibit 2
 23 before?
 24 A. I believe that I have.

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1 Q. Is it true that you've never seen it
 2 before January 12, 2022?
 3 MR. GOLDBERG: Objection to form.
 4 Mischaracterizes the testimony.
 5 A. It is not true to the best of my
 6 recollection.
 7 Q. Is it true that you didn't list this
 8 document in your reliance materials?
 9 A. That is correct.
 10 Q. And you have a specific list of
 11 reliance materials called Court Filings;
 12 correct?
 13 A. Correct.
 14 Q. And this is not on that list, nor is
 15 any other pronouncement of the court; correct?
 16 A. Correct.
 17 Q. I want you to turn with me to page 14
 18 of Exhibit 2.
 19 Are you there, Dr. Stiroh?
 20 A. Not yet. If you just give me a
 21 minute.
 22 I have page 14 in front of me.
 23 Q. If you look at the second line --
 24 sentence of that page, of Exhibit 2, the court's

<p style="text-align: right;">Page 126</p> <p>1 opinion, it says, and I quote, The court finds 2 that for prescription drugs, the mere 3 identifying and marketing a drug as the generic 4 equivalent to a branded pharmaceutical listed in 5 the Orange Book, and then selling that generic 6 equivalent when it contains a contaminant not 7 included in the Orange Book listing, constitutes 8 a breach of express warranty. 9 Did I read that correctly? 10 A. I believe so, yes. 11 Q. Did you consider that finding in your 12 analysis and the opinions in your report? 13 A. To the best of my recollection, I had 14 reviewed this document. 15 It does not have a specific role for 16 my opinions with respect to my economic 17 conclusions regarding economic losses. 18 Q. So whether or not there's a breach of 19 express warranty for the reasons set out by the 20 court did not influence or impact your opinions 21 at all; correct? 22 MR. GOLDBERG: Objection to form. 23 Asked and answered. 24 A. In my opinions evaluating the economic</p>	<p style="text-align: right;">Page 128</p> <p>1 economic loss damages, if any. 2 I don't know the basis for what the 3 court takes into account. I know the basis for 4 what I take into account in reaching that 5 opinion. 6 Q. Can you explain to me why you read and 7 then ignored the court's finding that these 8 drugs are, as it puts it, economically 9 worthless? 10 Why did you ignore that? 11 MR. GOLDBERG: Objection to form. 12 Mischaracterizes the testimony, and 13 argumentative. 14 A. I don't think it is right to say that 15 I ignored it. I reviewed this document. 16 I was asked to offer my opinion as an 17 economist about whether economic loss damages 18 can be determined with information and methods 19 common to the class. 20 I approached that in an independent 21 manner, considering what I as an economist would 22 review to reach an opinion about economic loss 23 damages, and I have done that. 24 Q. By "independent," do you mean at odds</p>
<p style="text-align: right;">Page 127</p> <p>1 loss to consumers, that is correct. 2 Q. Turn to page 20 of Exhibit 2, please. 3 Let me know when you're there. 4 A. I have page 20. 5 Q. You see the second full paragraph that 6 begins with the words, This court finds...? 7 A. I see that. 8 Q. The court wrote as follows, and I 9 quote, This court finds that contaminated drugs 10 are economically worthless at the point of sale 11 by virtue of the dangerousness caused by their 12 contamination, regardless whether the sold VCDs 13 actually achieved the medical purpose of 14 lowering blood pressure. 15 Did I read that correctly? 16 A. I believe so. 17 Q. Did you consider that finding by the 18 court anywhere in your analysis or opinions? 19 A. I reviewed this document. I did not 20 rely on it for reaching my opinions. 21 My opinions are based on my training 22 and experience as an economist, and I have 23 reached independent opinions about the economic 24 value of the products at issue and how to assess</p>	<p style="text-align: right;">Page 129</p> <p>1 with the court? 2 A. I do not mean at odds with the court. 3 MR. GOLDBERG: Note my objection. 4 Q. Do you see the sentence that follows, 5 which reads, Put differently, contaminated 6 drugs, even if medically efficacious for their 7 purpose, cannot create a benefit of the bargain 8 because the contaminants in their dangerous 9 effects were never bargained for? 10 Did I read that correctly? 11 A. I believe that you did. 12 Q. Did you consider that finding by the 13 court in your report or any part of your 14 analysis? 15 A. I reviewed this document for the 16 purposes of my report and my opinions. 17 I consider the -- independently, the 18 economic information that is available and reach 19 an opinion based on my training and experience 20 as an economist. 21 Q. So you disagree when the court writes 22 that the -- that the consumer didn't receive a 23 benefit of his or her bargain? 24 You fundamentally agree with that and</p>

<p style="text-align: right;">Page 130</p> <p>1 believe that there was some benefit; correct?</p> <p>2 MR. GOLDBERG: Objection to form.</p> <p>3 Ambiguous.</p> <p>4 A. I don't know what the framework is</p> <p>5 that the judge takes into account in reaching a</p> <p>6 legal opinion.</p> <p>7 I do know what the framework is that I</p> <p>8 take into account, and my economic framework</p> <p>9 leads me to the opinion that it is not correct</p> <p>10 to assume that the drugs were uniformly</p> <p>11 worthless to all purported class members.</p> <p>12 Q. But you understood that, unlike you,</p> <p>13 Dr. Conti took this for what it says, that the</p> <p>14 drugs are economically worthless?</p> <p>15 You understand that she accepted what</p> <p>16 the court found; correct?</p> <p>17 A. I understand that she has assumed the</p> <p>18 drugs are economically worthless, and I have</p> <p>19 explained in my report why as a matter of</p> <p>20 economics that is not a valid assumption to</p> <p>21 make.</p> <p>22 Q. But if the court hired you,</p> <p>23 Dr. Stiroh, to be the court's expert and</p> <p>24 directed you that the drugs were worthless, you</p>	<p style="text-align: right;">Page 132</p> <p>1 MR. GOLDBERG: Objection to form.</p> <p>2 Speculation.</p> <p>3 A. I will say again that is just so far</p> <p>4 outside my experience, that I cannot imagine</p> <p>5 that scenario happening.</p> <p>6 In my experience, economists are</p> <p>7 brought into legal proceedings to give an</p> <p>8 economist's point of view, and where I have been</p> <p>9 retained, that is what I have done, including in</p> <p>10 this matter.</p> <p>11 I have never been asked to assume a</p> <p>12 value and then asked to opine on that value.</p> <p>13 I have been asked to consider whether</p> <p>14 economic loss damages can be determined with</p> <p>15 information common to the class, and it is my</p> <p>16 opinion that economic loss damages, being the</p> <p>17 difference between the price paid and the value</p> <p>18 received, vary class member by class member and</p> <p>19 cannot be determined with information common to</p> <p>20 the class.</p> <p>21 Q. Doctor, didn't you tell me earlier</p> <p>22 today and write in your report that you offer no</p> <p>23 legal opinions and don't venture into the legal</p> <p>24 framework of what the proper measure of damages</p>
<p style="text-align: right;">Page 131</p> <p>1 would then ascribe the value of zero to them in</p> <p>2 your financial loss model that you and I went</p> <p>3 through earlier, wouldn't you?</p> <p>4 MR. GOLDBERG: Objection to form.</p> <p>5 Mischaracterize the testimony.</p> <p>6 A. That is wholly outside my experience</p> <p>7 or any work that I have ever undertaken.</p> <p>8 If I were retained by the court, and I</p> <p>9 have been retained by antitrust authorities, I</p> <p>10 still offer an independent economic analysis</p> <p>11 that may or may not comport with the legal</p> <p>12 framework because the legal framework is outside</p> <p>13 of my experience.</p> <p>14 What the court does with that would</p> <p>15 be, I think, up to the court to decide.</p> <p>16 I have never in my experience been</p> <p>17 told what opinion to reach and then offered that</p> <p>18 opinion.</p> <p>19 Q. Dr. Stiroh, respectfully, if the court</p> <p>20 instructed you that the drugs in question here,</p> <p>21 the VCDs in this MDL, are economically worthless</p> <p>22 because of a legal principle, could you not then</p> <p>23 ascribe a zero value and compute the loss</p> <p>24 exactly as Dr. Conti did?</p>	<p style="text-align: right;">Page 133</p> <p>1 is? Didn't you tell me that?</p> <p>2 MR. GOLDBERG: Objection to form.</p> <p>3 Mischaracterizes the testimony.</p> <p>4 A. I believe that I told you that. I</p> <p>5 don't think my answer in any way differed from</p> <p>6 that.</p> <p>7 To the extent that there was</p> <p>8 confusion, my opinions are economic opinions,</p> <p>9 and I offer them in the context of economics.</p> <p>10 I am not opining for the court on what</p> <p>11 the appropriate legal context is.</p> <p>12 Q. Dr. Stiroh, I'm not confused. I'm</p> <p>13 reading your language.</p> <p>14 And it says the following: I also do</p> <p>15 not opine on the legal issues relating to the</p> <p>16 proper measure of damages or on which measure</p> <p>17 should be used.</p> <p>18 Those are your words in paragraph 5 of</p> <p>19 your report.</p> <p>20 And so what I'm positing before we</p> <p>21 break for lunch is, if the court tells you that</p> <p>22 the proper measure to be used is to take the</p> <p>23 actual price paid for the drug, reduce it by its</p> <p>24 economic worth, which in this case is zero, and</p>

<p>Page 134</p> <p>1 then calculate the loss, is that something you 2 could do? 3 MR. GOLDBERG: Objection to form. 4 Asked and answered. 5 A. If I were asked to perform a 6 calculation and told what numbers to sum up, I 7 could do that. 8 If I were told to call that result 9 economic losses, I would not be comfortable 10 offering that opinion because, in my opinion, 11 that summation of numbers is not economic 12 losses. 13 MR. HONIK: All right. Good time to 14 break. Let's go off the record. 15 THE VIDEOGRAPHER: The time right now 16 is 1:25 p.m. We are off the record. 17 (Luncheon recess at 1:25) 18 19 20 21 22 23 24</p>	<p>Page 136</p> <p>1 consider specifically what the proper measure of 2 damages might be, for example, for a warranty 3 base claim, correct? Do you remember telling me 4 that? 5 MR. GOLDBERG: Objection to form. 6 Mischaracterizes the testimony. 7 A. I did not opine on what the 8 appropriate measure of damages would be for a 9 warranty claim. 10 To the extent that the Court finds 11 that the work and the measures of damages that I 12 have considered are relevant, then the work that 13 I have done is relevant to those claims. 14 Q. I'm sorry, I -- I thought you started 15 out by saying that you didn't offer an opinion 16 about what the measure of damages would be for a 17 warranty claim. Is that -- that part right? 18 A. That's not what I said. I said I 19 didn't offer an opinion on what the correct 20 measure of damages would be for a warranty 21 claim. 22 I do have opinions on the economic 23 considerations and economic loss damages, or 24 damages measured as differences in financial</p>
<p>Page 135</p> <p>1 AFTERNOON SESSION 2 (2:04) 3 LAUREN J. STIROH, Ph.D., 4 resumed, having been previously duly 5 sworn by a Notary Public, was 6 examined and testified further 7 as follows: 8 THE VIDEOGRAPHER: Time now is 9 2:04 p.m. We are back on the record. 10 CONTINUED EXAMINATION BY MR. HONIK: 11 Q. Dr. Stiroh, a while before we broke 12 for lunch and we spent some time talking about 13 the two different models that you described for 14 me, namely financial loss and diminution of 15 value, I was actually asking you some questions 16 that pertain to some of the specific theories of 17 liability in this case. 18 Do you remember we talked a bit about 19 that? 20 A. Probably not with sufficient clarity. 21 To continue on that conversation, I would need 22 to hear questions again. 23 Q. Of course. And one of the things you 24 told me, or confirmed, is that you didn't</p>	<p>Page 137</p> <p>1 outcomes. 2 And to the extent that my opinions and 3 work related to those measures of damages are 4 relevant to what a Court would consider for a 5 warranty claim, then that work would apply. But 6 I have not been the person that says, This is 7 the damages for a warranty claim. 8 MR. HONIK: Jeff, can I trouble you to 9 read just the very beginning part of that 10 response? I tried to get it, but I -- I -- 11 I was exasperated and didn't get it down. 12 (The record was read back.) 13 MR. HONIK: Stop there for a minute. 14 Q. I don't think that's what you said, 15 Dr. Stiroh, is it? 16 A. It is not. 17 Q. You said you did not, that's right. 18 Jeff, she said, I did not. 19 MR. GOLDBERG: Hang on. 20 MR. HONIK: Can you read it again 21 slowly starting with, I did not offer. 22 (The record was read back.) 23 Q. Okay. Next question, you ready, 24 Dr. Stiroh?</p>

<p style="text-align: right;">Page 138</p> <p>1 Did you offer an opinion on what the 2 correct measure of damages are for an unjust 3 enrichment claim in this case? 4 MR. GOLDBERG: Objection to form. 5 Calls for a legal opinion. 6 A. I have an understanding of what the 7 measure of damages for unjust enrichment are, 8 and it is expressed at least under romanette ix, 9 on page 8 in my report. 10 Q. What is that measure or calculation? 11 A. I understand unjust enrichment damages 12 to be the portion of a benefit conferred by a 13 plaintiff on a defendant which it would be 14 unjust for the defendant to retain. 15 Q. Did you actually perform a calculation 16 to determine whether or not unjust enrichment 17 damages exist in this case? 18 A. I have considered what Dr. Conti wrote 19 in her report about the methods that she says 20 she would apply to calculate unjust enrichment 21 damages, and I have considered what she said in 22 her deposition regarding how the variables that 23 she thinks would be relevant, and I have 24 opinions related to the -- what she purports to</p>	<p style="text-align: right;">Page 140</p> <p>1 your report? 2 A. In that answer, I was referring to 3 paragraphs 65 through 72. There is also a 4 discussion in my summary of opinions under 5 romanette ix, which is on page 8. 6 Q. Do you agree that if the unjust 7 enrichment formula or calculation used by 8 Dr. Conti reflected profits, that the formula 9 would then be complete according to you? 10 A. No. 11 The formula that Dr. Conti puts in her 12 report, in my view, is a superficial formula of 13 profits. She says little more than profits are 14 revenues minus costs. 15 Calculating unjust enrichment damages, 16 even if starting -- if starting with profits as 17 part of that measure, there needs to be a way of 18 assessing what the relevant revenues are, and 19 assessing what the relevant costs are, and in 20 the pharmaceutical industry, both of those 21 measures can be very complicated. 22 There is a complex supply chain. 23 There are differences in the business structures 24 wholesaler to wholesaler, or retailer to</p>
<p style="text-align: right;">Page 139</p> <p>1 do, that are expressed in my report. 2 Q. Do you have any opinions about the 3 correct measure of unjust enrichment damages, 4 separate and apart from whatever criticism you 5 may have of what Dr. Conti did on unjust 6 enrichment? 7 A. Are you asking me do I have opinions 8 about the quantum of unjust enrichment damages, 9 if any, or the methods? 10 Q. No. I'm asking you how you would 11 measure unjust enrichment. 12 MR. GOLDBERG: Objection to form. 13 Ambiguous. 14 A. In Section Roman V of my report, I 15 have a discussion of the retail pharmacy and 16 wholesaler damages related to plaintiff's theory 17 of liability and unjust enrichment, and in that 18 section, I describe my understanding of unjust 19 enrichment damages and the flaws that I see in 20 Dr. Conti's description of what she would do to 21 assess unjust enrichment damages, and I explain 22 the ways in which what she has set forward are 23 incomplete. 24 Q. What paragraph are you referring to in</p>	<p style="text-align: right;">Page 141</p> <p>1 retailer, such as the costs and the relevant 2 costs for each entity might differ depending on 3 the defendant, depending on the time period, 4 depending on the product that is being sold, and 5 the channel of distribution through which it 6 reached a wholesaler and then ultimately a 7 retailer. 8 Q. That's your complete answer? 9 A. Yes. 10 Q. Dr. Stiroh, did you arrive at an 11 opinion about the proper measure of damages for 12 Consumer Product Act damages? 13 MR. GOLDBERG: Objection to form. 14 Calls for legal opinion. 15 A. I do not offer an opinion on the 16 correct legal framework for damages for Consumer 17 Product Act damages. 18 Q. Dr. Stiroh, do you offer an opinion 19 anywhere in your report about the proper measure 20 of damages for common law fraud? 21 MR. GOLDBERG: Objection to form. 22 Calls for a legal opinion. 23 A. I do not offer an opinion on the 24 proper legal damages for common law fraud.</p>

<p style="text-align: right;">Page 142</p> <p>1 Q. Is therapeutic benefit synonymous with 2 economic worth, in your opinion? 3 A. For a pharmaceutical product, 4 therapeutic benefit is a significant component 5 of economic worth. 6 Q. And how do you go about measuring it? 7 MR. GOLDBERG: Objection. Ambiguous. 8 A. For purposes of an economic analysis 9 that takes therapeutic benefit into account, I 10 would consider the relative therapeutic benefits 11 of one product compared to an alternative, and 12 need information from a consumer, or the doctor 13 of the consumer, that describes the 14 alternatives. 15 A component of damages that considers 16 what a consumer would take in the alternative to 17 Valsartan would have to consider what the 18 therapeutic value of that alternative was and 19 whether it was equivalent to the Valsartan that 20 they took, and differences in the therapeutic 21 value would have to be accounted for. 22 Assessing what those differences are, 23 would require, I think, a medical opinion, not 24 just an economic opinion.</p>	<p style="text-align: right;">Page 144</p> <p>1 would need to be to get to the same level of 2 blood pressure management. 3 Q. Have you seen that input in this case 4 from any medical experts? 5 A. I have not seen any input in the 6 materials that I have reviewed. 7 Q. Have you ever had an engagement or 8 consultation in which you had such medical input 9 to arrive at a dollar value for therapeutic 10 value of a prescription drug? 11 MR. GOLDBERG: Objection. Vague. 12 A. I have not worked on a matter that had 13 a sufficiently similar fact profile where the 14 measure of harm includes a potential diminution 15 of value that comes from differences in health 16 outcomes where that would need to be valued, but 17 it is something that would need to be valued in 18 this matter. 19 Q. Have you ever so much as heard or read 20 about a reported case, in the economic or legal 21 literature, which done -- which has done what 22 you just described, namely, gotten medical input 23 in order to arrive at a dollar value for 24 therapeutic benefit in a prescription drug?</p>
<p style="text-align: right;">Page 143</p> <p>1 Q. And in what way would you be able to 2 translate that economic analysis into dollars 3 and cents? 4 How do you value that in dollars? 5 MR. GOLDBERG: Objection. Ambiguous. 6 A. For -- considering -- I'm sorry, I 7 guess I need you to say what the -- what it is 8 that you want me to value in dollars. 9 Q. You said that therapeutic benefit, 10 while not synonymous with economic worth, is a 11 significant component. 12 I'm asking you whether and how that 13 translates or could be translated into dollars 14 and cents. 15 A. We know, from expenditures on the 16 products at issue, that consumers valued the 17 therapeutic benefits of the products at least as 18 much as the price paid for them. 19 The -- if there is a difference in 20 therapeutic benefits measured, for example, by 21 differences in the ability to manage blood 22 pressure, then I could translate that into 23 dollars and cents, with input from a medical 24 expert, by considering what the expenditures</p>	<p style="text-align: right;">Page 145</p> <p>1 A. Yes. Generally, I am aware of various 2 economic papers that look at the costs of 3 treating certain indications and the costs of 4 managing health outcomes. It is not a field 5 that I specialize in. 6 I have encountered articles depending 7 on other cases that I have worked on that have 8 overlapped with health sciences, but that 9 economic concept of putting dollar values on 10 either -- certainly on mortality, as I mentioned 11 in my report, but the -- the costs of treating 12 different types of medical conditions, and the 13 costs of treating them under different 14 approaches to controlling that medical 15 condition, is something that I think is fairly 16 common in health economics. 17 Q. You don't hold yourself out to be a 18 health economist, do you? 19 A. I don't call myself a health 20 economist. I am an economist that has expertise 21 working in some industries that relate to health 22 sciences. 23 I would consider this case to be a 24 matter like that, where I bring my experience as</p>

<p style="text-align: right;">Page 146</p> <p>1 an economist to a case that involves health 2 outcomes. 3 Q. You know, of course, that that's all 4 Dr. Conti does, she's a health economist, don't 5 you? 6 A. I recall her testifying something 7 along the lines of that is all she does. 8 Q. And -- and you saw her bibliography in 9 which she authored literally hundreds of papers 10 and other contributions to the literature in 11 health economics. Right? 12 A. I have read her report. I have to say 13 I'm not sure I paged through her bibliography 14 ever, but I take your word for it. 15 Q. Do you agree that equilibrium price 16 from a classical economic standpoint is set by 17 the intersection of supply and demand? 18 A. I do. 19 Q. And do you agree that according to 20 economic theory, for a consumer product -- and 21 we're talking generally -- for a consumer 22 product to have economic value, demand for the 23 product must exist and supply must be allowed to 24 meet that demand?</p>	<p style="text-align: right;">Page 148</p> <p>1 involved in this case, and my expertise is in 2 economics and I have focused my analysis on 3 materials that are relevant to my economic 4 analyses. 5 Q. In listing your various reliance 6 materials, unless I missed it, I -- I do not 7 note your having relied on any of the U.S. Code 8 as it pertains to the introduction of drugs into 9 the supply chain. Have you? 10 A. I do not rely on any of the U.S. Code 11 as it pertains to the introduction of drugs into 12 the supply chain for the purposes of my opinions 13 that I'm offering in this report. 14 Q. Are you -- are you, nonetheless, 15 familiar with any aspects of federal law as it 16 concerns the ability for a drug manufacturer to 17 introduce into the legal class of trade a 18 prescription drug? 19 A. I have some familiarity with the 20 regulations concerning transactions in 21 pharmaceuticals, and entry of either new 22 pharmaceutical products or generic 23 pharmaceutical equivalents to existing 24 pharmaceutical products.</p>
<p style="text-align: right;">Page 147</p> <p>1 A. I disagree. 2 Q. I didn't see among your reliance 3 materials your having relied upon -- unless I 4 missed it -- with the exception, I think, of 5 Dr. Chan, you -- you didn't read any of the 6 defense class experts in this case. Have you? 7 A. My team and I have reviewed the expert 8 reports that are listed in paragraph 6. I don't 9 recall others and certainly not that I have 10 reviewed, if there are -- I just don't think 11 that I have, no. 12 Q. Did you review the defense class 13 expert report prepared by Dr. Lambert, who is 14 both a Ph.D. chemist, an expert in the 15 pharmaceutical supply chain, a cGMP, and CMC 16 expert? 17 A. I don't believe so. 18 Q. Do you understand that in this case, 19 there are any number of pharmacy industry 20 experts with a variety of expertise in how the 21 supply chain works, how cGMP compliance occurs, 22 how CMC occurs, how FDA regulations impact this 23 case? Are you aware of that generally? 24 A. I'm aware that there are more experts</p>	<p style="text-align: right;">Page 149</p> <p>1 I have familiarity based on my prior 2 work, but it is not something that I am 3 intending to put forward opinions related to. 4 Q. And certainly in this case, you didn't 5 rely upon any of those laws or regulations in 6 forming your opinions here, correct? 7 A. That is correct. 8 Q. Do you -- do you disagree that those 9 laws have an impact on determining whether 10 there's a legitimate supply curve for a 11 particular prescription drug? 12 MR. GOLDBERG: Objection to form. 13 Ambiguous. 14 A. Can you say how you are using the 15 phrase, "legitimate supply curve"? 16 Q. Sure. Do you think that there are any 17 laws that impact the ability of a manufacturer 18 to sell a drug in interstate commerce? 19 A. My understanding is that there are. 20 Q. And what impact, so far as you 21 understand, would those laws have on 22 determining, from an economic standpoint, the 23 legitimacy of producing a supply of a 24 prescription drug and, in turn, having a supply</p>

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1 curve?

2 MR. GOLDBERG: Objection to form.

3 Ambiguous.

4 A. With respect to this case, are you

5 asking me?

6 Q. No.

7 MR. GOLDBERG: Same objection.

8 A. I am aware that there are consumers in

9 the United States who seek to buy prescription

10 drugs outside of the United States for

11 consumption inside the United States.

12 That is a -- from an economic point of

13 view, that is supply of a product that could be

14 taken into account in doing an economic analysis

15 of supply and demand.

16 Q. Are you familiar with the drug now

17 long banned called fen-phen?

18 A. I am not.

19 Q. That was a prescription diet drug that

20 caused a certain type of heart damage, that's

21 been long banned in the United States.

22 Do you have an opinion, as an

23 economist, what the value of that drug is, if

24 I'm not able to get it lawfully here?

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1 A. I don't have a fully formed opinion

2 because I have never considered this scenario

3 before.

4 The components of value, though, if it

5 is something that you desire to get,

6 notwithstanding the fact that you can't get it

7 here, that tells me, as an economist, it has

8 value to you as a consumer.

9 Q. Your -- your economic opinion is that

10 if it's unlawful for me to obtain, and no doctor

11 will give me a prescription, that fen-phen still

12 has some dollar value. Is that your opinion?

13 A. My opinion is that if you want it, or

14 a consumer wants it, that product has value to

15 you.

16 Q. Let me ask the question differently.

17 In my hypothetical for fen-phen, is it lawful

18 for someone to sell it, a manufacturer, and

19 receive money for it?

20 A. I don't know. That -- you're asking

21 me now a legal opinion. And my opinions are

22 rooted in economics, and economic value comes

23 from somebody wanting a product.

24 Q. Well, respectfully, Dr. Stiroh, you

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1 don't limit your views in this case to purely

2 economic principles. Your essential thesis here

3 is that class certification isn't available.

4 That's a legal question, isn't it?

5 MR. GOLDBERG: Objection to form.

6 A. Can you say again what my fundamental

7 opinion is?

8 Q. Sure. You're familiar with Rule 23 of

9 the Federal Rules of Civil Procedure, aren't

10 you?

11 A. I am.

12 Q. You -- you've written on that, haven't

13 you?

14 A. I have written on the economics of it.

15 Q. Well, you've written specifically

16 about case law, haven't you?

17 A. I have written specifically about

18 various cases, but it is -- my writings are

19 related to the economics that were used in the

20 cases and considered by the court.

21 Q. Dr. Stiroh, your writings relate to

22 the interplay between the class certification

23 rule, Rule 23, and economics, extensively,

24 haven't you?

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1 A. I have written on the economics of

2 class certification, and I agree with you that

3 class certification is something that takes

4 place in a legal context.

5 Q. That's a -- that's a very curious way

6 to put it, because, you know, as I read your

7 opinions, you write for -- just for example,

8 Economic loss damages to members of the consumer

9 or third-party payor classes, if any, cannot be

10 assessed on a class-wide basis using information

11 and methods common to the proposed class.

12 Is that your language?

13 A. It is.

14 Q. And I gather you've probably written

15 that sentence numerous times before, right?

16 MR. GOLDBERG: Objection to form.

17 Ambiguous.

18 A. I have not.

19 Q. "Methods common to the proposed

20 class," is that an economic phrase or a legal

21 phrase?

22 A. It may be a legal phrase. In my

23 sentence when I said that the class-wide

24 damages, from my perspective, that aspect, is

<p style="text-align: right;">Page 154</p> <p>1 the economic part of it, whether the same words 2 would be used in a legal context or not. 3 Q. "Cannot be assessed on a class-wide 4 basis," is that a legal phrase or an economics 5 phrase? 6 A. It is the same answer I just gave you. 7 My assignment, as described in my report, was to 8 consider whether economic damages where I 9 have -- or economic harm, where it is -- I have 10 defined what I understand that to mean, can be 11 assessed on a class-wide basis, and that has 12 meaning to me as an economist, but my answer, 13 then, to the question is rooted in economics, 14 and it is an economic finding, not a legal one. 15 Q. What does class-wide basis mean? 16 A. As I use it, it means for the class as 17 a whole. 18 Q. And how is that different in your 19 mind, as you use it, from individual basis? 20 A. An individual basis would be to an 21 individual class member, and class-wide basis is 22 to the class as a whole. 23 Q. Is that the extent of your 24 understanding?</p>	<p style="text-align: right;">Page 156</p> <p>1 context of responding to a commonality argument. 2 The work that I do is based on 3 economics and then is used by a legal team in 4 the legal context in whatever way they feel is 5 most appropriate based on their experience and 6 understanding. 7 Q. Yeah, that's not really what I'm 8 asking you. I'm simply asking if we can agree 9 that the shorthand way to refer to your 10 application of economic principles to this 11 aspect of class certification that you've been 12 speaking at length about is referred to as 13 commonality. That's all I'm asking. 14 MR. GOLDBERG: Objection -- 15 Q. Do you agree with that? 16 MR. GOLDBERG: Objection to form, 17 asked and answered. Calls for a legal 18 opinion. 19 A. I guess I don't know that to be true 20 in all cases. Or even in this one. 21 I have an understanding that if the 22 lawyers or the court is considering whether 23 there is a predominance of common issues, that 24 an economist's report and opinions may factor</p>
<p style="text-align: right;">Page 155</p> <p>1 A. Sufficient to answer your question, 2 yes. To the extent that you will expand the 3 context, I may have a different answer, but in 4 the context in which I understood you to ask it, 5 that is the -- 6 Q. Do you understand -- 7 A. If I could just finish the answer so 8 it makes sense. 9 MR. GOLDBERG: Hang on, Ruben. She's 10 not finished the answer. 11 Q. Let me know when you're done. 12 THE WITNESS: I'm sorry. If you could 13 just mark that my answer was incomplete, 14 there, that would be good. I don't -- I've 15 lost my train of thought for it. 16 Q. Are you addressing what's commonly 17 referred to as the commonality requirement, in 18 the sentence we just went over? 19 MR. GOLDBERG: Objection to form. 20 Calls for a legal opinion. 21 A. I have an understanding that when 22 doing work related to the class certification 23 phase of a litigation, that the work that I do 24 is most frequently used by the legal team in the</p>	<p style="text-align: right;">Page 157</p> <p>1 into the legal opinions on that subject. 2 Q. Now you've introduced another legal 3 term, "predominance." Do you know what that 4 means? 5 MR. GOLDBERG: Objection to form. 6 Calls for a legal opinion. 7 A. I understand it is a term that is 8 included in class certification findings, and I 9 have an understanding, from a layperson, of what 10 that means. I don't -- wouldn't say I have a 11 legal understanding, because I'm not a lawyer. 12 Q. Well, you do understand, though, don't 13 you, that this issue, or business of 14 commonality, needs to apply, on the one hand, to 15 liability issues, and on the other hand, to 16 damage issues. Do you understand that much? 17 MR. GOLDBERG: Objection to form. 18 Calls for a legal opinion. 19 A. I have an understanding that a court 20 may consider whether the liability theories and 21 defenses are common to the class, and a court 22 may consider whether there are individual issues 23 and potentially weigh the common issues against 24 the individual issues to assess from a legal</p>

<p style="text-align: right;">Page 158</p> <p>1 perspective which ones dominate.</p> <p>2 Q. You do understand that they fall into</p> <p>3 two buckets, right? That you have to</p> <p>4 demonstrate this commonality concept on</p> <p>5 liability, and separately for damages. Do you</p> <p>6 get that?</p> <p>7 MR. GOLDBERG: Objection. Calls for a</p> <p>8 legal opinion.</p> <p>9 A. I don't -- I don't get that from an</p> <p>10 economic perspective. I work on class</p> <p>11 certification matters where I have an assignment</p> <p>12 that I carry out, and then whether that is used</p> <p>13 by the legal term to assess common issues on</p> <p>14 liability or common issues with respect to</p> <p>15 damages, that is up to the legal team.</p> <p>16 Q. Do you agree that whether the</p> <p>17 manufacturers in this case who have produced the</p> <p>18 VCDs adhere to cGMP in making them is a --</p> <p>19 presents a common question of fact or law?</p> <p>20 MR. GOLDBERG: Objection to form.</p> <p>21 Calls for a legal opinion.</p> <p>22 A. I don't have an opinion on that.</p> <p>23 Q. Do you have an opinion whether</p> <p>24 nitrosamines, a probable human carcinogen, can</p>	<p style="text-align: right;">Page 160</p> <p>1 to form. Calls for a legal opinion.</p> <p>2 A. I don't have an opinion on that.</p> <p>3 Q. Do you -- do you know whether it's a</p> <p>4 common question of fact or law whether the VCDs</p> <p>5 were adulterated within the meaning of the</p> <p>6 Federal Food, Drug, and Cosmetic Act?</p> <p>7 MR. GOLDBERG: Objection to form.</p> <p>8 Calls for a legal opinion.</p> <p>9 A. I don't have an opinion on that. I</p> <p>10 have an understanding that not all of the drugs</p> <p>11 at issue or all of the lots of the drugs at</p> <p>12 issue may have contained any of the impurities</p> <p>13 at issue, and I have a discussion of what that</p> <p>14 means for Dr. Conti's opinions. I don't have an</p> <p>15 opinion as to the facts surrounding that issue.</p> <p>16 Q. Do you disagree that it's a common</p> <p>17 question of fact or law to determine whether the</p> <p>18 VCDs in question were misbranded?</p> <p>19 MR. GOLDBERG: Objection to form.</p> <p>20 Calls for a legal opinion.</p> <p>21 THE WITNESS: Did he ask me do I have</p> <p>22 an opinion or understanding? Can you</p> <p>23 repeat. Or sorry.</p> <p>24 Q. I asked you if you agree --</p>
<p style="text-align: right;">Page 159</p> <p>1 present a common question of fact or law?</p> <p>2 MR. GOLDBERG: Objection to form.</p> <p>3 Calls for a legal opinion.</p> <p>4 A. I don't have an opinion on that.</p> <p>5 Q. Do you have an opinion whether it's a</p> <p>6 common question of fact or law whether the VCDs</p> <p>7 in this case were contaminated with NDMA or</p> <p>8 NDEA?</p> <p>9 MR. GOLDBERG: Objection to form.</p> <p>10 Calls for a legal opinion.</p> <p>11 A. I don't have an opinion on that. I</p> <p>12 consider in my report the possibility that not</p> <p>13 all products included the impurities NDMA and</p> <p>14 NDEA in quantities that have been alleged to</p> <p>15 cause an increase in the risk of cancer, and I</p> <p>16 have opinions that stem from the -- or that --</p> <p>17 that talk about how that interplays with the</p> <p>18 economic outcomes.</p> <p>19 Q. Do you agree that it's a common</p> <p>20 question of fact or law whether the defendant</p> <p>21 manufacturers in this case were aware, or should</p> <p>22 have been aware, of the potential for</p> <p>23 nitrosamine formation prior to 2018?</p> <p>24 MR. GOLDBERG: Objection. Objection</p>	<p style="text-align: right;">Page 161</p> <p>1 A. Oh.</p> <p>2 Q. -- that whether or not the VCDs in</p> <p>3 question here are misbranded is a common</p> <p>4 question of law or fact.</p> <p>5 MR. GOLDBERG: Again, object to form.</p> <p>6 Calls for a legal opinion.</p> <p>7 A. I don't think I even understand how</p> <p>8 your question is constructed. Whether --</p> <p>9 whether I'm being asked to agree with the</p> <p>10 statement, or being asked to agree that the</p> <p>11 issue is a common issue.</p> <p>12 I don't have an opinion, I think, on</p> <p>13 either. But I will say I don't think I</p> <p>14 understood the question.</p> <p>15 Q. Dr. Stiroh, the fact is, you don't</p> <p>16 question that there are common questions of fact</p> <p>17 and law that would support certifying a class on</p> <p>18 liability grounds. Correct?</p> <p>19 MR. GOLDBERG: Objection to form.</p> <p>20 Calls for a legal opinion.</p> <p>21 A. I don't offer opinions on that. I</p> <p>22 have opinions in my report related to the</p> <p>23 assignment I was asked to undertake.</p> <p>24 And the assignment was to consider</p>

<p style="text-align: right;">Page 162</p> <p>1 whether damages from economic losses or 2 differences in financial outcomes can be 3 determined with information common to the class, 4 and it is my opinion that they cannot be 5 determined with information common to the class, 6 and you would need individualized information 7 for -- from purported class members. 8 Q. Right. You said that multiple times. 9 And the reason for that is because according to 10 you, you'd have to value the therapeutic benefit 11 on the one hand, and the various risk factors 12 that can only be viewed through the individual 13 consumer. Right? 14 MR. GOLDBERG: Objection to form. 15 Mischaracterizes the testimony. 16 A. That is one of the reasons why you 17 need individual information. 18 Q. I'm sorry, you're saying I'm correct? 19 A. Your full statement was not correct, 20 but I do agree with you that you have stated 21 some of the reasons why you would need 22 individual information to properly assess 23 damages in this matter from an economic 24 standpoint.</p>	<p style="text-align: right;">Page 164</p> <p>1 the reasons you've written and we've talked 2 about, but if it turns out that the measure of 3 damages is financial loss, in the way you've 4 outlined to me, and you assume or accept that 5 the value of these drugs is zero, then one 6 could, quite readily, with common evidence, 7 proof, arrive at damages. Correct? 8 A. I disagree. If the measure of damages 9 is determined to be financial loss, and thus, as 10 we discussed this morning, you compare the 11 financial position of class members as they were 12 and the financial positions as they would have 13 been had they not consumed the at-issue VCDs, 14 you have to consider, Are there other variables 15 that change. 16 The other variable that would change 17 is what product would they consume instead of 18 the VCD to manage their blood pressure. That is 19 what is missing from what Dr. Conti did. 20 If you assume away or say that there 21 would not be any management of blood pressure, 22 then the comparison of situations at -- as they 23 are, and the situations as they would be, would 24 have to consider what happens to patients if</p>
<p style="text-align: right;">Page 163</p> <p>1 Q. Yeah. Before we broke for lunch, and 2 you and I looked together at what Judge Kugler 3 wrote about the economic worthlessness of the 4 drug and the concept that the drugs were worth 5 zero because of the failure of the benefit of 6 the bargain, you don't disagree that if that 7 ends up being the measure of damages, that that 8 subject is subject to common proof, do you? 9 MR. GOLDBERG: Objection to form. 10 Mischaracterizes the testimony. Calls for 11 a legal opinion. 12 A. Can you say it again, or may I ask the 13 court reporter to repeat that question. 14 Q. Sure. Judge Kugler is correct that 15 the drugs are economically worthless for the 16 reasons you and I looked at together and, 17 therefore, have a value of zero that, arising in 18 class damages, is a simple matter of common 19 proof. Correct? 20 A. I don't agree with you. 21 MR. GOLDBERG: And note my objection 22 as calling for a legal opinion. 23 Q. Well, I know that you don't agree with 24 the premise and the foundation for that, for all</p>	<p style="text-align: right;">Page 165</p> <p>1 they stop taking blood pressure medication, and 2 do they have adverse health outcomes that then 3 would also have different financial outlays than 4 they currently did when their blood pressure was 5 managed. 6 Q. Dr. Stiroh, are you aware that in the 7 marketplace when these contaminated drugs were 8 sold, and afterwards, that there were 9 uncontaminated generic forms of Valsartan 10 available? Are you aware of that? 11 A. I am aware that there are other forms 12 of Valsartan that are not alleged to have the 13 impurities, yes. 14 Q. And you are aware that in addition to 15 these uncontaminated generic forms of Valsartan, 16 there were a whole host of other ARBs, drugs of 17 this class, that control blood pressure, 18 correct -- 19 A. I'm aware of that -- 20 Q. -- available to consumers? 21 And you are aware that there were also 22 branded or innovator drug -- drugs available to 23 treat these conditions as well, correct? 24 A. I am aware of the presence of other</p>

<p style="text-align: right;">Page 166</p> <p>1 ARBs and the presence of a branded Valsartan 2 product. 3 Q. Do you agree with the statement that 4 when these drugs were sold between 2012 and 5 their removal from the market in 2018, the 6 contaminated forms of it, that no consumer was 7 aware if the drugs were contaminated? 8 A. Did you ask me if I am aware of that 9 or I agree with that? 10 Q. Is there a difference for you? 11 A. I think if you asked me if I'm aware, 12 you are stating a fact that I'm -- I don't know 13 to be true. 14 And if you're asking me if I am 15 aware -- if -- well, either way, I don't know 16 that it is true about what consumers understood 17 to be included in their Valsartan-containing 18 drugs as I sit here today. 19 Q. Do you have any facts or evidence to 20 share with us under oath that any consumer, 21 between 2012 and 2018, had any basis to 22 understand that their Valsartan contained 23 nitrosamines? 24 A. That is not a subject on which I am</p>	<p style="text-align: right;">Page 168</p> <p>1 purposes of my report. 2 Q. Well, I want you to assume in a 3 hypothetical that that is what they claim. 4 And I want to then ask you, on the 5 basis of that assumed fact, if it's conceivable 6 to you that the manufacturers didn't know there 7 were nitrosamines in their Valsartan pills, but 8 you believe that consumers might have known that 9 fact. Is that your statement? 10 MR. GOLDBERG: Objection to form. 11 Argumentative. 12 A. That is not my statement. 13 Q. Okay. Let me ask you a different 14 question. 15 Can you -- do you believe, as a matter 16 of economics, that if there's a binary choice 17 given to a consumer to buy, in this case, with 18 knowledge, a VCD that's contaminated with a 19 carcinogen and the exact same VCD that is 20 uncontaminated with any carcinogen, that there's 21 any consumer who would rationally select the 22 contaminated one? 23 A. I could envision a scenario in which 24 that happens, yes.</p>
<p style="text-align: right;">Page 167</p> <p>1 offering testimony. I don't have information to 2 share with you as I sit here today on that 3 subject. 4 Q. Do you think for a split second that a 5 single consumer knew about it and none of the 6 manufacturers did? Because that's what they 7 claim, you know. 8 MR. GOLDBERG: Object- -- 9 Q. You know that, right? 10 MR. GOLDBERG: Objection to form. 11 Foundation. Argumentative. 12 A. Are you asking do I know what is 13 claimed by manufacturers? 14 Q. Are you aware that the manufacturers, 15 uniformly in this case, claim that they didn't 16 know and couldn't know of the presence of 17 nitrosamines in their own products during the 18 relevant class period? Are you aware of that? 19 A. I don't think -- 20 MR. GOLDBERG: Objection to form. 21 A. -- I have reviewed information that -- 22 or at least that I recall as I sit here, on what 23 the defendant manufacturers are stating. It is 24 not something that I recall reviewing for</p>	<p style="text-align: right;">Page 169</p> <p>1 Q. Okay. Can you tell us, under oath, in 2 what scenario would a rational person pick the 3 contaminated VCD. 4 A. A scenario in which that may happen is 5 if the VCD that contains impurities is priced 6 lower than the VCD with -- without impurities, 7 and a consumer, in consultation with their 8 doctor, is informed that the level of impurities 9 is not likely to change their health comes -- 10 health outcomes in any meaningful way, that a 11 consumer may decide to save money by choosing a 12 product that has impurities in it. 13 Q. Do you know facts that support that 14 having occurred here ever? 15 A. I have examples in my report where I 16 talk about similar types of comparisons where 17 consumers choose between organic products and 18 products that contain pesticides, where 19 pesticides may include elements that could have 20 risks for human health outcomes. 21 And consumers make different choices 22 in different scenarios, but we can observe 23 market differences in prices. We observe 24 organic vegetables being sold, and we observe</p>

<p>Page 170</p> <p>1 vegetables that have been exposed to pesticides 2 being sold. 3 I have an example where economists 4 have measured differences in housing prices, 5 where houses are located in an area where there 6 is a higher incidence of leukemia than other 7 areas, and economists can observe and measure 8 the differences in prices that would be 9 attributable to the added risk in one geographic 10 area to another geographic area. 11 The section in my report that 12 describes other examples of where economists 13 have measured and priced risk I have in my 14 report as an indication that economists do look 15 at these types of things. 16 The presence of risk doesn't render a 17 product worthless. The presence of risk has 18 been measured by economists in other factors. 19 It's not appropriate to make the assumption that 20 Dr. Conti did. It's not appropriate to assume 21 worthlessness because of the presence of a risk. 22 Q. In order to price the presence of a 23 risk, doesn't a consumer need to know that the 24 risk exists?</p> <p>Page 171</p> <p>1 A. In the examples that I gave you, I was 2 envisioning that the economist prices the risk. 3 The -- whether the consumer prices the 4 risks, there are examples where the consumer 5 could know about a risk, and in those scenarios, 6 we can see a divergence in price and consumption 7 patterns of products that are deemed more or 8 less risky. 9 Q. Dr. Stiroh, respectfully, you didn't 10 answer my question. In order for either a 11 consumer or an economist, on an assumption, to 12 price or place a value on risk, to exercise that 13 choice, you have to have knowledge of the risk, 14 do you not? 15 MR. GOLDBERG: Objection to form. 16 Ambiguous. 17 A. To price the risk, an economist would 18 have an understanding or an assumption regarding 19 the risk profile, yes. 20 Q. That's right. In order to 21 affirmatively choose to live in an area with 22 high leukemia because of environmental factors, 23 you'd have to know about that risk in order to 24 take it or assume it or exercise a choice around</p>	<p>Page 172</p> <p>1 it, correct? 2 A. To do an economic study and draw the 3 conclusion that a price differential is due to 4 risk, you would have built into that some 5 expectation regarding information that is known 6 about the risks. 7 Q. Have you seen a single shred of 8 evidence in this case that any consumer, during 9 the relevant class period, proposed class 10 period, was aware of the presence of 11 nitrosamines in these Valsartan-containing 12 drugs? 13 A. I am not aware of any information that 14 indicates that. 15 Q. Let's bring up -- go into your 16 document if you would, and pull up -- just find 17 it -- bear with me. It's a -- it should be a 18 Tab 3. And it's a section of the United States 19 Code. 20 MR. GOLDBERG: Is this 331 or 351? 21 MR. HONIK: 331. 22 MR. GOLDBERG: Okay. 23 (Prohibited Acts, 21 USCA, Section 24 331, was marked Stiroh Exhibit 3 for</p> <p>Page 173</p> <p>1 identification, as of this date.) 2 Q. Dr. Stiroh, do you have what's been 3 marked as Exhibit 3? 4 Dr. Stiroh, have you ever laid eyes on 5 21 United States Code Annotated Section 331? 6 A. I don't have a particular recollection 7 of it. I may have seen it before. 8 Q. Do you see at the top, it's part of 9 the Federal Food, Drug, and Cosmetic Act? 10 Do you see that? 11 A. I see a heading, Chapter 9, Federal 12 Food, Drug, and Cosmetic Act, is that what 13 you're referring me to? 14 Q. Yes, ma'am. And underneath it, it 15 should say Subchapter 3, Prohibited Acts and 16 Penalties. 17 Do you see that? 18 A. I do. 19 Q. And the construct for this, as a 20 prohibited act piece of litigation, is to set 21 out what's prohibited. 22 You see where it says, The following 23 acts and the causing thereof are prohibited, 24 colon?</p>
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<p style="text-align: right;">Page 174</p> <p>1 You see that?</p> <p>2 A. I do.</p> <p>3 Q. And the very first prohibited act</p> <p>4 that's listed is as follows: The introduction</p> <p>5 or delivery for introduction into interstate</p> <p>6 commerce, of any food, drug, device, tobacco</p> <p>7 product or cosmetic that is adulterated or</p> <p>8 misbranded.</p> <p>9 Did I read that correctly?</p> <p>10 A. I believe you did.</p> <p>11 Q. Have you ever seen this statement</p> <p>12 in -- in the -- in federal law?</p> <p>13 A. I don't think I have set out to read</p> <p>14 federal law. The statement sounds familiar from</p> <p>15 Dr. Conti's materials. I may have seen it in</p> <p>16 this context as well, but I don't have a</p> <p>17 recollection of having reviewed this document.</p> <p>18 Q. Suffice to say you didn't give any</p> <p>19 weight or consideration to this prohibited act</p> <p>20 as set out in 21 USCA Section 331?</p> <p>21 A. I don't think that is accurate to say</p> <p>22 that I didn't give it weight. I didn't -- don't</p> <p>23 recall having reviewed this particular document.</p> <p>24 To the extent that it is something</p>	<p style="text-align: right;">Page 176</p> <p>1 adulterated drug can't be introduced into</p> <p>2 interstate commerce in the U.S., that that means</p> <p>3 such a drug, namely an adulterated drug, cannot</p> <p>4 have a legitimate supply curve in our market?</p> <p>5 MR. GOLDBERG: Objection to form,</p> <p>6 ambiguous.</p> <p>7 A. I have an understanding of what</p> <p>8 Dr. Conti was seeking to do when she removed the</p> <p>9 supply curve and called that legitimate supply.</p> <p>10 I have a discussion in my report about economic</p> <p>11 loss damages and that her analysis does not</p> <p>12 establish worthlessness.</p> <p>13 Whether there is a supply of product</p> <p>14 that the U.S. court allows, that is not the same</p> <p>15 as measuring the worth or value of drugs. The</p> <p>16 worth or value of drugs to consumers depends on</p> <p>17 their valuation of the products, not the supply</p> <p>18 of the products.</p> <p>19 I disagree with Dr. Conti on that</p> <p>20 point.</p> <p>21 Q. Did you hear me invoke Dr. Conti's</p> <p>22 name or any of her findings in my question,</p> <p>23 Dr. Stiroh?</p> <p>24 A. I don't recall if you said it. It is</p>
<p style="text-align: right;">Page 175</p> <p>1 that factors into Dr. Conti's opinions, I --</p> <p>2 that is something that I consider explicitly in</p> <p>3 my report.</p> <p>4 Q. This prohibits legally introducing,</p> <p>5 into the legal class of trade, an adulterated or</p> <p>6 misbranded product. Correct?</p> <p>7 MR. GOLDBERG: Objection. Calls for a</p> <p>8 legal opinion.</p> <p>9 A. I can see what the words are. I can't</p> <p>10 give you an opinion on what this prohibits or</p> <p>11 doesn't prohibit. I'm not a lawyer.</p> <p>12 Q. Doctor, you have a Ph.D. from Harvard</p> <p>13 in economics. Can you apply a plain meaning to</p> <p>14 what we read together sufficient to understand</p> <p>15 and agree that it prohibits introducing</p> <p>16 adulterated drugs in interstate commerce in the</p> <p>17 United States?</p> <p>18 MR. GOLDBERG: Same --</p> <p>19 Q. Can you draw that meaning from it?</p> <p>20 MR. GOLDBERG: Same objection.</p> <p>21 A. I can draw the plain English meaning</p> <p>22 from the words. I cannot give you a legal</p> <p>23 opinion related to it.</p> <p>24 Q. Would you agree that because an</p>	<p style="text-align: right;">Page 177</p> <p>1 relevant to my answer because my assignment in</p> <p>2 this case was to consider her opinions.</p> <p>3 Q. I'm not talking about your assignment</p> <p>4 now. I've asked you a profoundly simple</p> <p>5 question.</p> <p>6 And that is, as an economic principle,</p> <p>7 how can you have a legitimate supply curve of a</p> <p>8 product that is, by law, prohibited from</p> <p>9 entering interstate commerce?</p> <p>10 MR. GOLDBERG: Objection to form.</p> <p>11 Ambiguous.</p> <p>12 A. As a matter of economics, you could</p> <p>13 have a supply curve if there is supply of the</p> <p>14 product. What I take you to mean by "legitimate</p> <p>15 supply" is supply of a product that meets</p> <p>16 certain requirements.</p> <p>17 My understanding is that there was</p> <p>18 supply of VCDs that met those requirements, and</p> <p>19 the question is whether there -- the absence of</p> <p>20 supply from defendants causes products to be</p> <p>21 worthless.</p> <p>22 Q. You agree, if we were constructing,</p> <p>23 economically speaking, as you do all the time,</p> <p>24 and appropriately so, a but-for world in which</p>

<p style="text-align: right;">Page 178</p> <p>1 there's compliance with the law, and 2 specifically this prohibition of introducing 3 into interstate commerce adulterated drugs, that 4 in that but-for world, there is no legitimate 5 supply curve, correct? 6 A. I don't think that's correct. I think 7 you -- if you assume that the drugs that are 8 alleged to have impurities are not part of the 9 market, if you assume them away, there is still 10 supply of other Valsartan-containing drugs. 11 Q. You agree that if all of VHP's drug 12 products were adulterated, that none of them 13 could lawfully be in the U.S. legal class of 14 trade. Correct? 15 MR. GOLDBERG: Objection to form. 16 Calls for a legal opinion. 17 A. I don't know if I agree with that or 18 not. The facts that I take into account for my 19 report is that there were supply of drugs, there 20 were purchases of drugs, and I consider the 21 value of those drugs and how the value might be 22 diminished if consumers knew that there were 23 impurities in them. 24 It's a framework that I have worked</p>	<p style="text-align: right;">Page 180</p> <p>1 the totality of these two statements means that 2 you can't introduce adulterated drugs into the 3 U.S. interstate commerce and you can't get paid 4 for it? You don't understand that construct? 5 MR. GOLDBERG: Objection to form. 6 Calls for a legal opinion. 7 A. I guess as the plain English, if I 8 look at C, it seems to be illegal or prohibited 9 to receive it. Does that mean to you that it is 10 prohibited for a consumer to receive a drug? 11 I don't think that's what would be 12 intended. But if I, as an economist and not a 13 lawyer read it, that's what the words say. 14 Q. Suffice to say you didn't consider 15 21 USCA 331 A or C in your own analysis, right? 16 MR. GOLDBERG: Objection to form. 17 Asked and answered. 18 A. I did not rely on this document to 19 reach my opinions. My recollection is that 20 these statements are included in the materials 21 used by Dr. Conti, and so I consider her 22 materials and the opinions that she draws, in my 23 report, responding to those opinions. 24 Q. Can you show me or tell me where in</p>
<p style="text-align: right;">Page 179</p> <p>1 with in my report. The concept of legitimate 2 supply being necessary for value is something I 3 reject. 4 Q. Do you see, in Exhibit 3, that the 5 third prohibited act under C reads, The receipt 6 in interstate commerce of any food, drug, 7 device, tobacco product or cosmetic that is 8 adulterated or misbranded, and the delivery or 9 proper delivery thereof, for pay or otherwise, 10 is yet another prohibited act. 11 Do you see that? 12 A. I see where you are reading from the 13 document. 14 Q. And where it says, And the delivery or 15 proffered delivery thereof for pay, do you 16 understand that the prohibition against, in this 17 case, a drug manufacturer being paid for an 18 adulterated drug? 19 MR. GOLDBERG: Objection to form. 20 Calls for a legal opinion. 21 A. I guess I don't have an opinion on 22 what this means or a clear understanding of what 23 number C means. 24 Q. You don't have an understanding that</p>	<p style="text-align: right;">Page 181</p> <p>1 your report you discuss these prohibited acts 2 and their impact on your economic analysis? 3 MR. GOLDBERG: Ruben, while Dr. Stiroh 4 is looking at that, when you get a chance, 5 could we take a break for a minute or two? 6 MR. HONIK: At a -- at an appropriate 7 place to stop, which is soon, I think. 8 MR. GOLDBERG: Thanks. 9 A. In my report, I have a section 10 Roman II, "Background," that starts on page 9, 11 with paragraph 9. 12 Paragraph 10 has my understanding of 13 some of the facts at issue in this case, 14 including whether there are amounts of NDMA in 15 the VCDs at issue. 16 Q. Dr. Stiroh, I'm looking at 17 paragraphs 9 and 10, and this entire 18 "Background" section. I don't see a blessed 19 thing about the law prohibiting the introduction 20 of adulterated drugs in interstate commerce. 21 Where is -- where is it that you say it's in 22 there? 23 MR. GOLDBERG: Objection. 24 Argumentative.</p>

<p style="text-align: right;">Page 182</p> <p>1 A. I don't believe I used that phrase 2 anywhere in my report. 3 Q. Do you -- are you aware that 4 defendants' own expert on the pharmaceutical 5 supply chain, cGMP chemistry, agrees that this 6 construct in Exhibit 3 that we've been looking 7 at means that there could be no legitimate 8 supply curve? Are you aware of that? 9 A. I am not. 10 Q. Have you read or been informed 11 about -- by the defense, about the testimony of 12 Dr. Lambert in this case? 13 A. I'm not familiar with the testimony of 14 Dr. Lambert. 15 Q. And I don't -- I don't think you so 16 much as refer to him in your reliance materials, 17 correct? 18 A. I don't believe I refer to him in my 19 reliance materials. I don't recall having 20 relied on anything that he wrote. 21 Q. Would it surprise you, then, that he 22 agrees that if the FDA considers a drug to be 23 adulterated or misbranded, as set out here, and 24 the fact that it can't be lawfully introduced</p>	<p style="text-align: right;">Page 184</p> <p>1 you'd like, I can put it up on a share screen or 2 direct your attention to a paper exhibit, but 3 let me first begin by reading it. 4 And for the record, this is the 5 deposition -- sworn deposition testimony of 6 Dr. Lambert. It appears at page 104, beginning 7 at line 21, and the question was as follows: 8 And so does that not mean, 9 Dr. Lambert, that there can be no legitimate 10 supply curve, that is, an adulterated drug 11 cannot be legally introduced into the legal 12 class of trade in the United States? 13 And the witness, Dr. Lambert, for the 14 defense, said, So if it's determined by the FDA 15 that it is indeed adulterated, then I would 16 agree. 17 And so my question to you is, are you 18 in disagreement with Dr. Lambert that there can 19 be no legitimate supply curve by the application 20 of this law, and if so, if you do disagree, can 21 you tell us under oath why? 22 MR. GOLDBERG: Objection. Calls for a 23 legal opinion. 24 A. In my opinion as an economist, there</p>
<p style="text-align: right;">Page 183</p> <p>1 into interstate commerce, and the manufacturer 2 or supplier of that lawfully receives money, 3 that that means under that construct, it can't 4 be a legitimate supply curve? 5 MR. GOLDBERG: Objection -- 6 Q. Do you deny that? 7 MR. GOLDBERG: Objection to form. 8 Foundation. 9 A. Are you asking me if I deny what 10 somebody else said in testimony I haven't read? 11 Q. Yes. Do you have any basis to 12 disagree with what Dr. Lambert, on behalf of 13 defendants, told us under oath? 14 MR. GOLDBERG: Objection to form. 15 Assumes facts not in evidence. 16 A. I have a basis to disagree with 17 certain statements that you have made on the 18 grounds of them not being economic principles. 19 Whether they are legal principles, I 20 don't have a basis to agree with you or disagree 21 about whether somebody else in this case said 22 something or agreed to something when I have not 23 read their testimony. 24 Q. Well, let me read it to you, and if</p>	<p style="text-align: right;">Page 185</p> <p>1 is a supply curve if there is supply of 2 products, and -- or willingness to supply 3 products at different price points. That's what 4 a representation of a supply curve would be. 5 My understanding is that not all of 6 the VCDs at issue contained the NDMA and NDEA 7 impurities, and it is also my opinion, as an 8 economist, that whether there is supply of the 9 Valsartan-containing drugs at issue or not, 10 there is value that was received for the 11 products that were purchased and consumed. 12 Q. Dr. Stiroh, if Dr. Lambert is right 13 and you're wrong, that there is an illegitimate 14 supply curve, you'd agree that no equilibrium 15 price could be set, because you've already 16 confirmed that it requires the intersection of a 17 supply-and-demand curve. Right? 18 A. I would agree that an equilibrium 19 price is the intersection of a supply-and-demand 20 curve. I have disagreed with you about whether 21 there is still a supply curve for 22 Valsartan-containing drugs, and I disagree with 23 Dr. Conti that the absence of supply of certain 24 Valsartan-containing drugs implies that the</p>

<p style="text-align: right;">Page 186</p> <p>1 value of those products that were consumed by 2 consumers is zero. 3 Q. Dr. Stiroh, inasmuch as you're not a 4 cGMP expert, would you disagree with the idea, 5 in good manufacturing practices and by the 6 application of FDA regulations, that if you 7 can't guarantee the integrity, purity, safety 8 and efficacy of one lot or batch of drugs that 9 fail to meet cGMP, that that implicates and 10 causes all of the pills to be adulterated? 11 MR. GOLDBERG: Objection to form. 12 Ambiguous. Calls for a legal opinion. 13 A. The part of that that I agree with is 14 that I am not a cGMP expert. 15 I don't think I even followed the rest 16 of the question. 17 And -- I guess not sure why you would 18 ask my opinion with -- starting it out by saying 19 that you agree that I am not a cGMP expert. I 20 don't have opinions on that topic. 21 Actually, if we could take a break. 22 MR. GOLDBERG: Okay. The witness has 23 just asked to take a break, and I had asked 24 about ten minutes ago.</p>	<p style="text-align: right;">Page 188</p> <p>1 now -- 2 MR. HONIK: Thank you. 3 THE VIDEOGRAPHER: The time right now 4 is 3:11 p.m. We are off the record. 5 (A recess was taken from 3:11 to 6 3:28.) 7 THE VIDEOGRAPHER: Time right now is 8 3:28 p.m. We are back on the record. 9 MR. HONIK: Jeff, for the benefit of 10 the record, I've had Dr. Stiroh pull a 11 transcription about which I questioned her 12 earlier, and we're going to be marking this 13 Exhibit 4. 14 (Transcript of deposition of William 15 J. Lambert was marked Stiroh Exhibit 4 for 16 identification, as of this date.) 17 THE COURT REPORTER: It's now marked. 18 Q. Dr. Stiroh, we had been talking a bit 19 about this idea of equally -- equilibrium 20 pricing and the intersection of 21 supply-and-demand curves. 22 As an economist -- I don't want to 23 oversimplify it, but the way one would graph a 24 supply curve or put that on the graph, you'd be</p>
<p style="text-align: right;">Page 187</p> <p>1 MR. HONIK: I just have some quick 2 follow-up to that, and then we can break. 3 Q. The reason I've asked you, Doctor, is 4 that you keep repeating that some but not all of 5 the drugs, as to some of the manufacturers, was 6 contaminated, and I'm merely asking if you have 7 any awareness of the rules and regulations of 8 current manufacturing practices which renders 9 all drugs from a facility as adulterated if you 10 can't guarantee the safety of each and every 11 product coming out of that facility. 12 You either are or are not aware of 13 that. That's what I've asked. 14 MR. GOLDBERG: Objection to form. 15 Calls for a legal opinion. 16 Q. Are you? 17 A. I am not aware of that, and I am not 18 offering opinions on that. 19 Q. Thank you. 20 MR. HONIK: How much time of a break 21 would you like, Seth? 22 MR. GOLDBERG: Why don't we take 23 ten minutes. 24 THE VIDEOGRAPHER: The time right</p>	<p style="text-align: right;">Page 189</p> <p>1 able to see, in the case of a consumer product, 2 the actual movement of a line representing sales 3 in the marketplace. Correct? 4 A. No. I think you are -- either I am 5 confused from your question or you're confusing 6 concepts in your question. 7 A demand curve and a supply curve that 8 intersects at a point that we call the 9 equilibrium price does not show movement along a 10 line. 11 You can imagine it as the amounts that 12 would be consumed at different price points from 13 the standpoint of consumers, or would be 14 supplied at different price points from the 15 standpoint of suppliers. What we observe in 16 data is what happens at the intersection. 17 Q. That's right. And you got me on the 18 words. All I meant to ask you, in -- however 19 inartfully, and we can go around on this if 20 you'd like, but all I want to understand is, if 21 it isn't -- if you aren't able, as an economist, 22 to plot on a graph a supply curve. 23 A. I'm sorry. You're asking me if it is 24 possible to plot on a graph a supply curve?</p>

<p style="text-align: right;">Page 190</p> <p>1 Q. Yeah.</p> <p>2 A. Yes.</p> <p>3 Q. And when you do so, if the value of a</p> <p>4 particular point on that graph is zero, is at</p> <p>5 zero, is -- does that mean that there's no</p> <p>6 supply of that item or product?</p> <p>7 A. No. There may be a point where</p> <p>8 quantity demanded is zero and the price could be</p> <p>9 quite high. And you would expect that there</p> <p>10 would be many suppliers that would be willing to</p> <p>11 supply the product at that high price, but there</p> <p>12 would be no consumer demand for it.</p> <p>13 Q. Did you hear me ask you anything about</p> <p>14 pricing?</p> <p>15 MR. GOLDBERG: Objection to form.</p> <p>16 Argumentative.</p> <p>17 A. I -- then I should have asked for</p> <p>18 clarification, what are you envisioning on the</p> <p>19 axes for a supply curve or a demand curve that</p> <p>20 would intersect.</p> <p>21 I imagined that they were intersecting</p> <p>22 at a point that gives you coordinates for price</p> <p>23 and quantity.</p> <p>24 Q. Okay. So let's try it again. I'm not</p>	<p style="text-align: right;">Page 192</p> <p>1 is something that Dr. Conti has created for this</p> <p>2 report. I don't understand it outside of the</p> <p>3 context of her report. And I hear you use it,</p> <p>4 and before, you objected to me saying her name.</p> <p>5 I have seen IQVIA data, and after the</p> <p>6 dates of recalls, it is apparent in the IQVIA</p> <p>7 data that it looks like there are sales of the</p> <p>8 products at issue. Whether that's a flaw in the</p> <p>9 data source or an actual fact, I cannot tell you</p> <p>10 as I sit here.</p> <p>11 You asked me if I have seen the data.</p> <p>12 I have seen it, and that is what I have</p> <p>13 observed.</p> <p>14 Q. Let -- let me ask the question this</p> <p>15 way. What's your definition of no supply curve?</p> <p>16 A. I don't have a definition of no supply</p> <p>17 curve. I have a definition of no supply. Which</p> <p>18 I think that you asked me earlier, and I agreed,</p> <p>19 that if supply is zero, that is no supply. That</p> <p>20 is not the same as there being no supply curve.</p> <p>21 A supply curve is a construct of the</p> <p>22 consideration of how much would be supplied by</p> <p>23 suppliers at different price points.</p> <p>24 Would be willing to be supplied.</p>
<p style="text-align: right;">Page 191</p> <p>1 talking about a demand curve, and I'm not</p> <p>2 talking about equilibrium pricing. I'm merely</p> <p>3 asking you if, as an economist, when you plot a</p> <p>4 supply curve on a graph, if -- if it's at zero</p> <p>5 on the horizontal axis and zero at the vertical</p> <p>6 axis, if that means there's no supply.</p> <p>7 A. Yes.</p> <p>8 MR. GOLDBERG: Objection.</p> <p>9 Q. Okay.</p> <p>10 Have you seen the sales of any of the</p> <p>11 at-issue VCDs after recall?</p> <p>12 A. Yes.</p> <p>13 Q. And do you agree that those sales are</p> <p>14 at zero in the case of the recalled manufacturer</p> <p>15 products?</p> <p>16 A. I have seen, in the IQVIA data, that</p> <p>17 there continue to be records of sales of the</p> <p>18 recalled products after the dates of recalls.</p> <p>19 Q. You don't agree that there was no</p> <p>20 supply, legitimate supply curve for ZHP VCDs</p> <p>21 after the recall?</p> <p>22 MR. GOLDBERG: Objection to form.</p> <p>23 Ambiguous.</p> <p>24 A. I think the term, "legitimate supply,"</p>	<p style="text-align: right;">Page 193</p> <p>1 Q. Do you agree that one of the ways to</p> <p>2 think about this case is to create a but-for</p> <p>3 world prior to the recall starting in 2018,</p> <p>4 going back to the beginning of manufacturing in</p> <p>5 2012, in which there's zero supply?</p> <p>6 MR. GOLDBERG: Objection to form.</p> <p>7 Ambiguous.</p> <p>8 A. I have considered that if the but-for</p> <p>9 world has zero supply of certain Valsartan</p> <p>10 products between 2012 and 2018, what</p> <p>11 implications that has for consumer expenditures.</p> <p>12 Q. Yeah, that's not really what I asked</p> <p>13 you.</p> <p>14 Could you, at my direction, supply a</p> <p>15 but-for or develop a but-for model in which</p> <p>16 there's zero supply, between 2012 and 2018, of</p> <p>17 Valsartan-containing drugs, yes or no? And then</p> <p>18 I have a follow-up question.</p> <p>19 A. I could construct a model, considering</p> <p>20 the scenario where there is zero supply of</p> <p>21 certain Valsartan-containing drug products, and</p> <p>22 consider the economic implications of that model</p> <p>23 for financial outcomes for consumers.</p> <p>24 Q. I don't know what the second part of</p>

<p style="text-align: right;">Page 194</p> <p>1 it is, but I take it you can -- you can create a 2 but-for world with zero VCD supplies. That much 3 you said you could do. Right? 4 A. I can do that. 5 Q. In that but-for world, is not the -- 6 the cost of that drug zero? 7 Isn't the -- excuse me, I misspoke. 8 Isn't the price of that drug zero? 9 A. No. 10 As an economic matter, the price for a 11 product that has been taken out of the market no 12 longer exists. 13 For a but-for world to be complete and 14 meaningful in a damages context, then you would 15 need to consider what consumers would purchase 16 instead of the product that they did purchase. 17 I can construct a damages model where 18 this but-for scenario is that there is no supply 19 of the Valsartan-containing drugs at issue. 20 For that to be a complete damage 21 model, I need to consider what do patients do to 22 manage their blood pressure in the absence of 23 the products that they actually did consume. 24 Q. Dr. Stiroh, you didn't even come close</p>	<p style="text-align: right;">Page 196</p> <p>1 estimate damages under a scenario where we 2 imagine removing the supply of 3 Valsartan-containing drugs. 4 To make that an economically valid 5 damage assessment, I would need to consider what 6 do consumers who purchase those drugs do in the 7 alternative. I would consider the prices they 8 would pay for alternative drugs, whether they 9 alternative -- they are alternative ARBs or 10 different VCDs other than the contaminated ones. 11 It is not true to say the price is 12 zero if there is no supply. There is -- price 13 does not exist in that case. That is 14 meaningless, to say that the price is zero. 15 Price is zero is a free good; price nonexistent 16 is for a product that doesn't exist. 17 Q. I understand your -- your answer. And 18 I think anyone listening to this will understand 19 it as well. 20 Why don't you pull up from your pile 21 of exhibits there, both Tabs 18 and 19, which 22 would be your invoicing in this case. 23 We're going to mark your exhibits -- 24 excuse me, your invoices as Exhibit --</p>
<p style="text-align: right;">Page 195</p> <p>1 to answering my question. 2 What I asked you to assume is not all 3 the things you ingrafted upon my hypothetical. 4 It's true, because you've already told me there 5 could be no equilibrium price where there's no 6 intersection of supply and demand, and having 7 informed me that you can create a but-for world 8 with zero supply, which means it will never meet 9 a demand curve, there can be no equilibrium 10 price. Correct? 11 MR. GOLDBERG: Objection to form. 12 Argumentative. Asked and answered. 13 Ambiguous. 14 A. No. 15 Acknowledging it's getting a little 16 late in the afternoon, that question was 17 absolutely meaningless from a standpoint of 18 economics. 19 I can create a but-for world -- 20 Q. I guess -- 21 A. Let me finish my answer, please. 22 MR. GOLDBERG: Hang on, Ruben. Hang 23 on, Ruben. The witness is talking. 24 A. I can create a but-for world and</p>	<p style="text-align: right;">Page 197</p> <p>1 Exhibit 5, and the summary that we prepared as 2 Exhibit 6. 3 Would you give that to our reporter, 4 please. 5 (Invoice from NERA Economic Consulting 6 was marked Stiroh Exhibit 5 for 7 identification, as of this date.) 8 (Summary of invoices was marked Stiroh 9 Exhibit 6 for identification, as of this 10 date.) 11 Q. Do you have Exhibits 5 and 6 in front 12 of you? 13 MR. GOLDBERG: Not yet, not yet. Hang 14 on. Wait one second, please. 15 Okay, go ahead. 16 Q. Do you have Exhibit 5, the collection 17 of invoices that were turned over to us? 18 A. I do. 19 Q. You're familiar with your own 20 invoicing for the work that you and your 21 associates at your firm did in this case? 22 A. I am. 23 Q. You reviewed them before today's 24 deposition?</p>

<p style="text-align: right;">Page 198</p> <p>1 A. I did.</p> <p>2 Q. The earliest of the activity on</p> <p>3 invoicing that I have relates to October of</p> <p>4 2020. Is that correct?</p> <p>5 A. The -- the first page of the project</p> <p>6 diaries that I have has an entry from me from</p> <p>7 September 15, 2020.</p> <p>8 Q. Does that correspond to the earliest</p> <p>9 point at which you did work on this matter?</p> <p>10 A. I expect I would have read the</p> <p>11 complaint prior to that date, but it is the --</p> <p>12 the first date that I recall once I had</p> <p>13 received -- been retained and received an</p> <p>14 assignment.</p> <p>15 Q. And the work that you did in this</p> <p>16 matter, Dr. Stiroh, you did perhaps hired by one</p> <p>17 counsel but you did it on behalf of all the</p> <p>18 defendants. Didn't you?</p> <p>19 A. Yes, that is correct.</p> <p>20 Q. And that's specifically set out in</p> <p>21 your report, is it not?</p> <p>22 A. Yes. My report, under "Assignment,"</p> <p>23 says, I've been asked for counsel for all</p> <p>24 defendants, and goes on from there.</p>	<p style="text-align: right;">Page 200</p> <p>1 A. I do.</p> <p>2 Q. Do you have any reason to dispute the</p> <p>3 amounts that are indicated or enumerated in</p> <p>4 Exhibit 6?</p> <p>5 A. I haven't gone through it and matched</p> <p>6 them up, but I don't have a reason to dispute</p> <p>7 them.</p> <p>8 Q. So, if the total of the invoice</p> <p>9 amounts for your work and that of your firm was</p> <p>10 \$1,369,114 through the end of calendar year</p> <p>11 2021, you would agree with that. Right?</p> <p>12 A. Yes.</p> <p>13 Q. How -- with what frequency did your</p> <p>14 firm issue invoicing for work done by NERA, your</p> <p>15 firm in this case?</p> <p>16 MR. GOLDBERG: Ruben, are you able to</p> <p>17 put the summary document up on the screen.</p> <p>18 I'm getting that request from people who</p> <p>19 are watching in on Zoom.</p> <p>20 MR. HONIK: Yeah, I'd be delighted to.</p> <p>21 Dave, are you able to do that?</p> <p>22 MR. STANOCH: It's in the public</p> <p>23 exhibit folder at Exhibit 6, but --</p> <p>24 MR. HONIK: Do you know how to pull it</p>
<p style="text-align: right;">Page 199</p> <p>1 Q. Do you know of any other economist</p> <p>2 that was engaged to do any work similar to your</p> <p>3 own by the defendants in this case?</p> <p>4 A. I'm not sure what you mean by that.</p> <p>5 Q. Are you the sole economist engaged by</p> <p>6 the defendants to prepare a report on whether or</p> <p>7 not damages can be ascertained on a class-wide</p> <p>8 basis?</p> <p>9 A. I am the only -- I'm the only one that</p> <p>10 I'm aware of, but I -- I don't know if they've</p> <p>11 engaged others.</p> <p>12 Q. And from my review of your own</p> <p>13 invoicing, the last of the invoices covers the</p> <p>14 period December ending last year, 2021. Is that</p> <p>15 correct?</p> <p>16 A. Yes.</p> <p>17 Q. Would you put Exhibit 6 in front of</p> <p>18 you.</p> <p>19 A. I have it.</p> <p>20 Q. This is a summary that we put together</p> <p>21 that's a simple computation or addition of the</p> <p>22 various invoice amounts from October of 2020</p> <p>23 through the end of December 2021.</p> <p>24 Do you see that?</p>	<p style="text-align: right;">Page 201</p> <p>1 up as a screen share?</p> <p>2 MR. STANOCH: Stand by.</p> <p>3 Q. There we go. Is -- is what you see on</p> <p>4 the screen, Dr. Stiroh, the summary that we</p> <p>5 marked Exhibit 6?</p> <p>6 A. It is what you marked as Exhibit 6.</p> <p>7 Looking at it now, I -- I'm not sure -- I see</p> <p>8 for January dash 21, 301,262.50. And if I look</p> <p>9 at an invoice that I think is intended to cover</p> <p>10 that period, I see 30,162.50.</p> <p>11 Q. Okay. If there's a computational</p> <p>12 error, then we'll correct it.</p> <p>13 A. If I can, then I think I need to</p> <p>14 correct my last answer. I did not dispute that</p> <p>15 these were accurate, and now I do.</p> <p>16 Q. The -- the question that I -- that I</p> <p>17 posed to you, which I don't think you answered</p> <p>18 as yet, is, with what frequency has NERA, on</p> <p>19 your behalf and on behalf of your associates,</p> <p>20 billed the defendants for your time? Has it</p> <p>21 been on a monthly basis?</p> <p>22 A. Generally, the invoices reflect a</p> <p>23 month's work. The frequency with which we get</p> <p>24 them out the door is not quite monthly, but</p>

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1 the -- the -- the period of coverage is
2 typically a month.
3 Q. Have you seen any invoicing for the
4 work of yourself and your team for any part of
5 2022?
6 A. Yes.
7 Q. When did you see such invoicing?
8 A. We are in the process of reviewing
9 those currently. I have not yet completed my
10 review of them. I have seen that they're in the
11 process of being prepared.
12 Q. And is that true for January 2022,
13 that is, you haven't billed for January 2022?
14 A. That is correct.
15 Q. Are you able to -- since you've seen
16 the invoicing, and you're auditing it, can you
17 tell me the number of additional hours that
18 reflect work of yourself and others at NERA in
19 2022?
20 A. Not by memory. There would be hours
21 associated with completing my report. But I
22 don't recall specifically what the hours were.
23 Q. Right. And all I'm asking you is to
24 estimate for me, if you can, how many total

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1 hours NERA is likely to bill from January 1,
2 2022, to the present, which would include the
3 finalization of your report, subsequent review,
4 any testimony of experts in this case,
5 preparation for today, anything else that you
6 might have done in -- in connection with your
7 engagement.
8 MR. GOLDBERG: Objection.
9 Q. How many hours would that total?
10 MR. GOLDBERG: Objection.
11 Speculation.
12 A. I think the total would be around,
13 say, 3,500 hours for all of NERA's work in this
14 matter. And so whatever is totaled up in the
15 invoices through December 2021 would be
16 subtracted off of that with the understanding
17 that that is sort of a ballpark guess.
18 Q. Understood.
19 Turn with me, in Exhibit 5, which is
20 the -- which are the invoices themselves, and I
21 just want to go through some of them to get a
22 flavor for what I'm looking at here.
23 There's something called "Project
24 Diary," dated November 24, 2020, and there's an

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1 invoice number US 48601P005.
2 Do you see that page, for example?
3 A. I might need you to say it again a
4 little bit slower. What is the invoice date
5 that you want me to look at?
6 Q. Let's try to do it this way. I think
7 it's the second page of Exhibit 5.
8 A. I have the second page --
9 Q. Let's do that.
10 A. I have the second page of Exhibit 5 in
11 front of me.
12 Q. In the right-hand upper corner, does
13 it say November 24, 2020?
14 A. It does.
15 Q. And do you see under your own name as
16 managing director, there's an entry, it says
17 December 15, 2020?
18 A. Yes.
19 Q. And the description of services
20 rendered is redacted, with the exception of the
21 word "discussion," with S.LI.
22 Do you see that?
23 A. Yes.
24 Q. Did you cause that redaction?

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1 A. I did not.
2 Q. Do you know why it was redacted?
3 MR. GOLDBERG: Objection. I mean,
4 that -- that calls for a legal conclusion.
5 And this is information that has been
6 marked confidential by counsel.
7 MR. HONIK: Nothing's been marked
8 confidential. I just have black lines. Do
9 you want to convey why this has been
10 redacted?
11 MR. GOLDBERG: You can ask the witness
12 the questions. I'm not here to testify.
13 MR. HONIK: I have asked her.
14 A. All right. But I thought you were
15 asking Mr. Goldberg. Sorry.
16 Q. Well, he -- he interrupted.
17 The question I asked was, why was this
18 redacted and what's in there? What -- what
19 service did you render on September 15, 2020?
20 MR. GOLDBERG: Let me object to the
21 extent you are being asked to provide
22 information not in a testifying capacity.
23 THE WITNESS: Now I answer?
24 MR. GOLDBERG: Yes.

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<p>1 A. My team and I spent time on this case 2 in a consulting capacity separate from the 3 assignment that I have described in my report. 4 It's my understanding that -- 5 Q. I don't -- I'm sorry, I don't 6 understand the distinction you're making. 7 MR. GOLDBERG: Well, counsel, that's 8 not really for Dr. Stiroh. We can talk 9 about this among lawyers. But -- but I'll 10 leave it at that. 11 If you'd like to go off the record, 12 I'm happy to do that, and we can talk about 13 it. 14 MR. HONIK: Well, I -- no, I'd like to 15 stay on the record. I think it's 16 permissible for me to ask about her work in 17 this case. 18 It's -- you've been billed for it. 19 It's in the invoice that's been produced to 20 us. I'd like to know what the work was 21 that relates to this case. 22 Q. Do you -- do you -- first of all, do 23 you know the answer to my question? 24 A. I have a general recollection of some</p>	<p>1 December 2021. 2 Q. Well, do you see, for example, the 3 time entries for an associate analyst by the 4 name of Nathan Evans? Do you see that? 5 MR. GOLDBERG: We're not on the same 6 page, Ruben. So -- are you talking about 7 the invoice dated December 8, 2021, or the 8 time -- 9 MR. HONIK: No, I'm talking about a 10 page called "Project Diaries." 11 A. I have a page called "Project Diaries" 12 that reflects time for Nathan Evans for 13 December 2021. 14 Q. Okay. But do you see the entries for 15 October 14 through October 20 are completely 16 redacted? 17 A. I'm sorry. I was looking at the wrong 18 one. I think -- let me catch up with you. If 19 you give me the dates for the entries, I think I 20 can find the page. The person and the dates for 21 the entries. 22 Q. October -- October 14 through 23 October 20, 2021. 24 A. I believe I have the correct page in</p>
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<p>1 of the work that was done that is not connected 2 with my assignment with respect to class 3 certification issues. 4 Q. So, are you saying that you had 5 multiple assignments from these same defendants? 6 MR. GOLDBERG: Counsel, I don't want 7 to belabor the point here. Just as you 8 have done with your experts, to the extent 9 Dr. Stiroh provided services for defendants 10 that were not related to the opinions in 11 her report, that information is redacted. 12 MR. HONIK: Is that the reason they 13 were redacted? 14 MR. GOLDBERG: I just represented that 15 to you. 16 Q. Dr. Stiroh, can you turn deeper into 17 the pile of invoices -- let me try to shorthand 18 way to -- shorthand way. 19 Can you go to project diaries dated 20 December 8, 2021. It's in- -- Invoice 21 Number US 53163P005. And I would estimate it's 22 about eight or ten pages from the back. 23 A. I have in front me a page with project 24 diaries with my time that encompasses</p>	<p>1 front of me. 2 Q. Do you see how all of Mr. Evans' time 3 for those dates are redacted? 4 A. I do. 5 Q. What does this work relate to that 6 caused it to be redacted, if not support for 7 this report? 8 MR. GOLDBERG: Again, counsel, that 9 information has been redacted because it 10 is -- does not pertain to Dr. Stiroh's 11 opinions and work in developing her 12 opinions and the report, and therefore, 13 it's been redacted. And -- it -- 14 Q. Let me ask a different question. 15 Doctor -- Dr. Stiroh, are you able, 16 you yourself, able to go through all of these 17 invoices and project diaries and, on your own, 18 separate out what was supporting, allegedly, 19 your report in this case that you proffered to 20 this point, and other work? Can you discern the 21 difference? 22 A. I could potentially do that, yes. 23 Q. What -- what criteria would you use to 24 distinguish work done in support of this report,</p>

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1 dated January 12 of this year, and any other
2 assignments that you may have received?
3 A. Work that I asked to be done for
4 purposes -- from -- to my staff for reviewing
5 information or data, or doing data analyses
6 related to my report, would be things that I
7 would consider in support of my work.
8 If there are tasks that counsel asked
9 of any of my team that was not coming at my
10 direction and not for purposes of my report,
11 that would be -- not be something I would
12 consider to be work for my report.
13 Q. Are you -- are you preparing another
14 report in this case?
15 A. I am not preparing another report in
16 this case.
17 Q. Have you, nonetheless, been asked to
18 undertake a different assignment in this case as
19 it relates to VCDs in this MDL?
20 MR. GOLDBERG: Objection to form. To
21 the extent that there's information or
22 services that Dr. Stiroh is providing that
23 are not pertaining to her opinions as a
24 testifying expert, that information is off

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1 limits.
2 MR. HONIK: It's just a yes or no.
3 I'm not going to ask her what it is.
4 MR. GOLDBERG: And that's the answer.
5 I just gave you answer, which is the
6 question is not a proper question.
7 MR. HONIK: You don't get to decide
8 what's a proper question or not.
9 I'd like Jeff to read it -- excuse me,
10 I'd like Jeff to read it back, please.
11 (The record was read back.)
12 MR. HONIK: It's MDL.
13 MR. GOLDBERG: Same.
14 Q. Without revealing what the nature or
15 name of that assignment is, are you able to
16 answer the question simply yes or no?
17 A. I have not been given an additional
18 assignment in this case.
19 DIR Q. Is that true from the beginning of your
20 engagement to the present?
21 MR. GOLDBERG: I'm -- I'm going to
22 instruct the witness not to answer, because
23 you're taking her down a road that is
24 misleading.

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1 I've given you the explanation for why
2 the information has been redacted. And
3 that's because it doesn't pertain to the
4 services Dr. Stiroh is providing for us in
5 the capacity as a testifying expert.
6 I will instruct the witness not to
7 answer --
8 MR. HONIK: She just testified --
9 MR. GOLDBERG: -- because you're just
10 going to -- you're just going to create a
11 record that is confused and misleading.
12 MR. HONIK: She's just testified under
13 oath that she's had no other assignment.
14 MR. GOLDBERG: Then that's -- that's
15 my point. That's my point.
16 MR. HONIK: That she's had a single
17 assignment.
18 MR. GOLDBERG: That's my point.
19 So you could move on, because I've
20 instructed her not to answer.
21 MR. HONIK: I -- I take that.
22 Q. Doctor, you apparently, some years
23 ago, were involved in a case called LaPoint
24 versus AmerisourceBergen Corp.

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1 Do you remember that case?
2 A. I do.
3 Q. And apparently in that case you were
4 hired by the plaintiff. The legal dispute
5 concerned a would-be merger between
6 two companies, plaintiff having a product called
7 a bedside point-of-care, a bar code product of
8 some sort, that was supposed to have been merged
9 or acquired by AmerisourceBergen.
10 Did I get that about right?
11 A. I don't remember those details. I
12 remember that there was a point-of-care bar code
13 product that was involved. I don't recall
14 the -- the aspects of the merger.
15 Q. That's right. And your -- your job as
16 an economist was to determine and -- and provide
17 economic support for the contention that but for
18 the merger, that -- that the company who made
19 this product, which was called Bridge, was
20 destined to remain a dominant force in that
21 particular market, and you were going to do some
22 economic calculations based on that premise.
23 Correct?
24 A. I -- I can't agree with you, just

<p style="text-align: right;">Page 214</p> <p>1 the -- with respect to I don't have the memory 2 of that. It -- every word you're saying brings 3 back more memories of it, but I don't -- it's a 4 while ago and I don't remember the specifics of 5 the case. 6 Q. Uh-huh. Why don't we -- have you seen 7 the -- the decision by the Court of Chancery of 8 Delaware in this case? 9 Ever? 10 A. I have. Some time ago. But I have. 11 Q. Right. And do you remember what 12 happened to your testimony and your work in that 13 case? Your report? 14 A. I do. 15 Q. Can you tell me what you remember 16 happening to it? 17 A. Yes. I had written a report. I can't 18 recall if it -- I think it might have had 19 damages in it. But it had an economic analysis, 20 in which I relied on the report of another 21 expert to supply certain inputs from my report, 22 particularly market share. 23 In discussions with the other expert, 24 I had -- was given an understanding of the</p>	<p style="text-align: right;">Page 216</p> <p>1 that I was working with, decided not to put my 2 report into evidence, and I did not testify to 3 it. 4 Q. But was it clearly known that this 5 reliance upon data was not data collected or 6 compiled by you but, in fact, by some other 7 expert? Was that well known and clear? 8 A. I don't know what you mean by "well 9 known." But certainly in my report, it was 10 referenced to the other expert, and the other 11 expert, I think, also had a report or opinion or 12 materials that were not included -- 13 Q. And -- 14 A. -- in the court materials. 15 Q. -- did you say that that other 16 expert's report was likewise pulled? 17 MR. GOLDBERG: Objection to form. 18 Mischaracterizes the testimony. 19 A. I don't recall what happened with the 20 other expert and his report. To the best of my 21 recollection, the information and circumstances 22 became apparent during his deposition, which 23 suggests that maybe he did have a report, but I 24 don't recall with certainty.</p>
<p style="text-align: right;">Page 215</p> <p>1 methodologies that he used to assess market 2 shares. 3 On the eve of trial, it became 4 apparent that what I had been given to 5 understand about his methodologies was not, in 6 fact, true, and his report was withdrawn. 7 Because his report was withdrawn and I 8 did not have confidence in the method by which 9 the data were collected, I did not feel I could 10 testify to the numbers in my report, and 11 together with counsel, we withdrew my report 12 from the case. 13 Q. So according to you, there was some 14 unreliable data that was used in your report, 15 and you -- you were pulled as an expert; is that 16 what you're saying? 17 MR. GOLDBERG: Objection to form. 18 Mischaracterizes the testimony. 19 A. That's not what I'm saying. The -- in 20 the course of vetting the data that I used in my 21 report, I was given to understand a set of 22 circumstances that I later understood to be 23 incorrect. 24 I, with -- together with the counsel</p>	<p style="text-align: right;">Page 217</p> <p>1 Q. Well, I thought you had testified a 2 moment ago under oath that his report was pulled 3 just like yours. Is that incorrect 4 understanding? 5 MR. GOLDBERG: Objection. 6 Mischaracterizes the testimony. 7 A. That is an incorrect understanding. 8 What I have indicated to you with respect to 9 this case, it was some time ago and my memory 10 isn't perfect. 11 My recollection is that for my report, 12 I, in consultation with the counsel that I was 13 working with, elected not to testify to it, 14 because I did not have faith in the numbers that 15 were drawn from a different expert's report. 16 I'm not telling you for a point of 17 fact what happened to that other expert's 18 report. 19 Q. I see. Well, why don't you actually 20 pull the -- the decision of the court out of the 21 pile of records there. It's Tab 11. And the 22 name of the case, again, is LaPoint versus 23 AmerisourceBergen. 24 And we'll get go ahead and mark that</p>

<p style="text-align: right;">Page 218</p> <p>1 as Exhibit 7.</p> <p>2 Do you now have the exhibit,</p> <p>3 Dr. Stiroh?</p> <p>4 A. Not just yet.</p> <p>5 MR. GOLDBERG: Ruben, it looks like</p> <p>6 you did not provide that document to us.</p> <p>7 MR. HONIK: Okay. Then why don't we</p> <p>8 go ahead and screen share it.</p> <p>9 Dave, do you have it?</p> <p>10 MR. STANOCH: Stand by.</p> <p>11 MR. HONIK: Thank you.</p> <p>12 Okay. Here's the opinion. We'll</p> <p>13 separately send it to -- to Jeff, and he'll</p> <p>14 mark it as Exhibit 7. This is next in</p> <p>15 order.</p> <p>16 As I mentioned earlier, it's from the</p> <p>17 Court of Chancery of Delaware. It's called</p> <p>18 LaPoint versus AmerisourceBergen Corp.</p> <p>19 Q. Do you see that, Dr. Stiroh?</p> <p>20 (Opinion in LaPoint v.</p> <p>21 AmerisourceBergen Corp. was marked Stiroh</p> <p>22 Exhibit 7 for identification, as of this</p> <p>23 date.)</p> <p>24 A. Yes, I do.</p>	<p style="text-align: right;">Page 220</p> <p>1 page 1 and so I can refresh my recollection of</p> <p>2 the summary of details of the case perhaps.</p> <p>3 Q. We can do that if you'd like.</p> <p>4 (Witness reviewing document.)</p> <p>5 MR. GOLDBERG: You want to scroll down</p> <p>6 a little bit, to the -- the -- that</p> <p>7 paragraph under Statement of Facts?</p> <p>8 MR. HONIK: Well, respectfully, this</p> <p>9 isn't your deposition. If --</p> <p>10 MR. GOLDBERG: Yeah, but as counsel,</p> <p>11 I'm allowed to -- as counsel, I'm allowed</p> <p>12 to review the documents that you're going</p> <p>13 to ask questions about. And since you</p> <p>14 didn't provide the document, I also need to</p> <p>15 see it.</p> <p>16 MR. HONIK: Okay. Well, we can email</p> <p>17 it to you right now. I mean, it's only</p> <p>18 about six or seven pages, and, Seth, you</p> <p>19 can take as much time as you'd like to</p> <p>20 review it. Is that what you want?</p> <p>21 MR. GOLDBERG: You can do that. I</p> <p>22 don't want you to ask questions until I've</p> <p>23 been able to review it.</p> <p>24 MR. HONIK: I think it's a colossal</p>
<p style="text-align: right;">Page 219</p> <p>1 Q. And you see the opinions authored by</p> <p>2 Judge Chandler? Do you remember Judge Chandler</p> <p>3 in the case?</p> <p>4 A. I don't think I had occasion to meet</p> <p>5 him.</p> <p>6 Q. That's right. That makes sense.</p> <p>7 MR. HONIK: Turn to page 5, please,</p> <p>8 Dave.</p> <p>9 MR. GOLDBERG: You going to let the</p> <p>10 witness review the document?</p> <p>11 MR. HONIK: If she would like, sure.</p> <p>12 MR. GOLDBERG: Why don't you give her</p> <p>13 a second and let her take a look at page 1</p> <p>14 and page 2 so that she has a chance to look</p> <p>15 at it.</p> <p>16 Q. Is that what you'd like to do,</p> <p>17 Dr. Stiroh? Do you want to review this opinion?</p> <p>18 Or it sounds like you may have remembered it</p> <p>19 fairly well, based on what you told me thus far.</p> <p>20 A. I don't remember the details of the</p> <p>21 case very well. I'll have to say I do remember,</p> <p>22 obviously, the circumstances, because it was</p> <p>23 unique in my history.</p> <p>24 If -- if you could just go back to</p>	<p style="text-align: right;">Page 221</p> <p>1 waste of time and a stalling tactic, but if</p> <p>2 you want to read it, I really don't care</p> <p>3 very much. I'm trying to wrap up</p> <p>4 Dr. Stiroh's deposition and get her out of</p> <p>5 there. We're nearly done.</p> <p>6 MR. GOLDBERG: Ruben, all we're --</p> <p>7 MR. HONIK: She's demonstrated to</p> <p>8 me --</p> <p>9 MR. GOLDBERG: Ruben, all we're doing</p> <p>10 is --</p> <p>11 MR. HONIK: Excuse me. She's --</p> <p>12 excuse me. She's demonstrated to me a</p> <p>13 rather keen recollection of this case. I'm</p> <p>14 not going to quiz her on the case. I'm</p> <p>15 going to focus on what she did and what</p> <p>16 she's already told us happened, which is</p> <p>17 that there was some data problem and she</p> <p>18 got pulled.</p> <p>19 And all I'm going to do is direct her</p> <p>20 to that part of the opinion that addresses</p> <p>21 it. It's a very narrow section.</p> <p>22 But if you want to read the entire</p> <p>23 report -- or, excuse me, opinion, we'll</p> <p>24 send it to you.</p>

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1 MR. GOLDBERG: Yeah, I -- I --
2 MR. HONIK: You can take as much time
3 as you like.
4 MR. GOLDBERG: I think all we wanted
5 to do is just take a quick scan of the
6 first page to get familiar with what the
7 case is.
8 And Mr. Stanoch had not shown us that
9 first paragraph.
10 MR. HONIK: There's no "we"; she
11 remembers it, you don't. If you want to
12 read it, read it.
13 MR. GOLDBERG: Like I said, I just
14 wanted to get familiar with the first page
15 here. I wanted Dr. Stiroh to familiarize
16 herself with it.
17 A. I have looked at the paragraphs that
18 are before me on this screen. Until looking at
19 this, I had not actually recalled that the
20 entire dispute came from a -- an acquisition.
21 I remembered the details about my
22 report and decision not to testify. And if you
23 ask me the question related to what is in this
24 decision, I can see if it -- I feel like I need

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1 to have more information about the background of
2 the case itself.
3 Q. Let's go to page 5, and we'll see if
4 you need more review.
5 And if you do, you'll tell me.
6 All right.
7 So -- hold on.
8 Yeah, go up a little bit. Sorry.
9 See where it says, B, Questions of
10 material fact relating to causation and damages?
11 A. I do.
12 Q. That's yes?
13 A. Yes.
14 Q. So you were -- you were a damage
15 expert on -- as to causation; do you remember
16 that?
17 A. I don't have an independent memory of
18 it. I'll have to say I -- I -- if you ask the
19 next question or see if there's something -- I
20 don't actually remember my specific assignment
21 without looking back at what the assignment was
22 that I had been given.
23 Q. Yeah. So, it says in the -- in the
24 second full paragraph, in the right-hand column,

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1 you see it's highlighted, it says, Plaintiff's
2 causation arguments are not helped by the
3 withdrawal of their key expert witness,
4 Dr. Lauren J. Stiroh, whose report was meant to
5 provide support for the contention that but for
6 a merger with ABC, Bridge was destined to remain
7 the dominant force in the BPOC market.
8 Do you see that?
9 A. I see where you are reading.
10 Q. Does that refresh your recollection
11 about what you were doing in the case?
12 A. It doesn't. I don't -- I don't have
13 any reason to disagree with what's written
14 there, but I don't have a recollection of the
15 work that I did, other than the ultimate
16 outcome.
17 Q. Yeah. So, the ultimate outcome is
18 that, as the judge wrote, virtually on the eve
19 of trial and after this motion had -- had been
20 filed, had been fully briefed, Plaintiffs
21 discovered that the data on which Dr. Stiroh
22 relied may not have been credibly gathered.
23 Plaintiffs no longer rely upon the conclusions
24 in this report.

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1 Did I read that correctly?
2 A. You did.
3 Q. Is there any mention about your
4 reliance upon data or conclusions or anything
5 from another expert in that paragraph?
6 A. In that paragraph, it mentions the
7 data on which I had relied. The data on which I
8 relied came from another expert.
9 Q. Okay. But you agree that the court
10 doesn't note that it came from another expert.
11 It only notes that it came from your report.
12 Right?
13 A. I don't think it does note that it
14 came from my report. It notes the data on which
15 I relied, and I am telling you, and I believe
16 the court knew, that it came from another expert
17 who might be referenced somewhere else in this
18 document. I don't know that as I sit here. But
19 the data on which I relied came from another
20 expert.
21 Q. Okay. You see where it says,
22 Plaintiffs no longer rely upon the conclusions
23 in this report?
24 That refers to your report, right?

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1 A. It does.

2 Q. So the data that the judge is writing

3 about that -- that was not credibly gathered was

4 in your report. Correct?

5 A. I can tell you that the data upon

6 which I relied was gathered by another expert.

7 It was the method by -- by which he had gathered

8 data that I found to be unreliable, and so I did

9 not testify to my report.

10 Q. Well, I'm now confused. Was the

11 method for gathering it unreliable, or was the

12 data itself unreliable, or both?

13 A. To the best of my recollection, the

14 method for gathering it was unreliable, and that

15 led me to conclude that the data itself would

16 not be a reliable input into a damages estimate.

17 Q. And you only discovered that after you

18 employed the data using the methodology which

19 you knew to be unreliable. Right?

20 A. No.

21 I did not -- when I used the data, I

22 did not know them to be unreliable. I was -- I

23 had vetted the data and the process.

24 What I was told about the process of

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1 data gathering turned out not to be the process

2 that had been employed. When I learned that a

3 different process that I felt was unreliable had

4 been employed, it was my opinion that the --

5 because the data gathering process was not

6 reliable, I could not rely upon the data and was

7 not willing to testify as to the damages that

8 used those data as an input.

9 MR. HONIK: Those are all the

10 questions I have of this witness. We're

11 going to keep the deposition open, hope

12 never have -- to have to revisit it, but

13 inasmuch as you withheld invoicing

14 information which needs to be supplemented,

15 we'll keep the record open.

16 You want to take a break and determine

17 if you have any questions?

18 MR. GOLDBERG: Yeah. Why don't we do

19 that. Why don't we come back in

20 ten minutes.

21 THE VIDEOGRAPHER: Time right now is

22 4:16 p.m. We are off the record.

23 (A recess was taken from 4:16 to

24 4:31.)

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1 THE VIDEOGRAPHER: Time right now is

2 4:31 p.m. We are back on the record.

3 EXAMINATION BY MS. KAPKE:

4 Q. Good afternoon, Dr. Stiroh. My name's

5 Kara Kapke. I'm counsel for CVS and Rite Aid,

6 and I have a few questions for you about your

7 opinions regarding Dr. Conti's unjust enrichment

8 opinions with respect to retail pharmacies and

9 wholesalers.

10 Where does therapeutic value fit into

11 the unjust enrichment analysis?

12 A. My understanding of unjust enrichment

13 damages, as described in my report, are the

14 portion of a benefit conferred by a plaintiff on

15 a defendant which would be unjust for the

16 defendant to maintain.

17 The portion, then, that would be -- my

18 understanding of just for the plaintiff -- for

19 the defendant to retain would be the benefit

20 that the plaintiffs received from the

21 therapeutic benefits of the drugs.

22 Q. I want to ask you specifically now

23 about Dr. Conti's unjust enrichment calculations

24 with respect just to pharmacies.

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1 Do you recall having opinions about

2 those calculations?

3 A. I do.

4 Q. And after you wrote those opinions,

5 did you have a chance to read Dr. Conti's

6 deposition transcript where she was asked

7 questions about her unjust enrichment opinions

8 with respect to pharmacies?

9 A. I did.

10 Q. After reading her report and

11 deposition transcript, what's your understanding

12 of how Dr. Conti calculated unjust enrichment

13 damages with respect to pharmacies from a

14 mechanical perspective?

15 A. I understand that she summed up

16 certain revenues received by pharmacies, from

17 her report, which reads as if she had intended

18 then to subtract relevant costs.

19 From her deposition, it seems to me

20 from reading that she does not think there are

21 relevant costs, and so she -- my understanding

22 of her opinion is that it is simply revenues

23 received without subtracting costs and without

24 any apportionment with respect to what part

<p>Page 230</p> <p>1 might be just or any consideration of a 2 therapeutic benefit that patients received. 3 Q. From -- after reading her report and 4 deposition transcript, what's your primary 5 criticism for how Dr. Conti describes her 6 methodology for calculating profits for the 7 pharmacies? 8 A. I would say it is too simplistic and 9 incomplete. It was not apparent, from reading 10 her report, that her opinion was that it was 11 essentially revenues that she thought were 12 unjust enrichment. 13 From reading her deposition, it is 14 apparent that she thinks that there are certain 15 costs that she thinks are not relevant, that I 16 think would be relevant for calculating profits 17 even before any apportionment. 18 Q. Not asking you to give an exhaustive 19 list, but what are some of those costs that you, 20 as an economist, would consider in a profits 21 calculation? 22 A. I think often and first and foremost 23 it would be the cost of goods sold, is quite 24 often the biggest component of costs.</p> <p>Page 231</p> <p>1 There are typically other types of 2 costs that are associated with delivering a 3 product to consumers. They could be cost of 4 storing the product, delivering the product, 5 operating the facility, but I think there are a 6 wide variety of categories. None of the 7 categories are included in Dr. Conti's 8 calculation. 9 Q. For purposes about thinking about the 10 cost of goods sold, does it matter if a pharmacy 11 acquired and paid for the product the day it 12 sold it to the customer, a month before, or a 13 year before? 14 A. Not from a standpoint of economics, 15 no. 16 Q. Why not? 17 A. The profits that are received are the 18 part of the revenue that the retailer gets to 19 hold on to, putting aside the question of 20 apportionment. The retailer does not benefit 21 from the entirety of revenue. They have to then 22 use that revenue to pay out their costs, and 23 there would not be the entirety of revenue as a 24 profit calculation.</p>	<p>Page 232</p> <p>1 Q. As an economist, have you ever seen 2 profits calculated without including the cost of 3 ingredients? 4 A. Not profits for a pharmaceutical 5 product, no. 6 Q. Have you ever seen an economics 7 textbook or scholarly piece of literature, or 8 anything like that, where someone measures 9 profits from an economics perspective without 10 considering the cost of ingredients? 11 A. No. For the highest level with no 12 detail, to say that profits are revenue minus 13 cost, it still has cost. 14 As part of that definition, from an 15 accounting point of view, which when we are then 16 applying economic theory to an actual case, we 17 typically would look at accounting data, and 18 that would start with a cost of goods sold and 19 other costs of delivering the product to 20 consumers. 21 MS. KAPKE: Thank you so much, 22 Dr. Stiroh. I don't have any further 23 questions. 24 THE WITNESS: Thank you.</p> <p>Page 233</p> <p>1 MR. HONIK: Any questions from anyone 2 else? 3 MR. GOLDBERG: I may have a question 4 or two, but I do need to take just a 5 two-minute break. Sorry. If we can go off 6 the record for two minutes. 7 THE VIDEOGRAPHER: The time right now 8 is 4:35 p.m. We are off the record. 9 (A recess was taken from 4:35 to 10 4:39.) 11 THE VIDEOGRAPHER: Time right now is 12 4:39 p.m. We are back on the record. 13 MR. HONIK: So Ms. Kapke is done 14 questioning. Are there any other questions 15 from defense counsel? 16 Seth? 17 MR. GOLDBERG: No. There are no other 18 questions from defense counsel. 19 MR. HONIK: Was that Leslie in the 20 room? 21 MR. GOLDBERG: No one else is in the 22 room at this time. Just myself, Kara -- 23 MR. HONIK: When we were off the 24 record, was there someone else in the room?</p>
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<p style="text-align: right;">Page 234</p> <p>1 MR. GOLDBERG: Leslie was in the room. 2 MS. KAPKE: She came in to talk to me. 3 MR. HONIK: Oh. 4 Okay. 5 EXAMINATION BY MR. HONIK: 6 Q. Dr. Stiroh, you were asked some 7 questions by Ms. Kapke, who represents CVS, 8 about the way in which profits were calculated 9 in an unjust enrichment model. 10 Are you aware that plaintiff sought 11 from the retailers the very costs that you 12 referred to, cost of goods, delivery cost, 13 storage, all the other items that you believe 14 might be incorporated in such a model, and -- 15 and we were not provided that? 16 In fact, the court, to this point in 17 the litigation, has not directed the retailers 18 to provide that. Were you aware of that? 19 MS. KAPKE: Object to form. I think 20 that misstates the record. 21 But go ahead and answer. 22 A. I'm not aware of what costs were 23 requested. I have considered what Dr. Conti 24 said, and it was my understanding from reading</p>	<p style="text-align: right;">Page 236</p> <p>1 benefits that come from specific plaintiffs. 2 But at a minimum, my understanding of 3 what she had set forward, the simplistic thing 4 that she put in her report, is not even what I 5 think she said in her deposition from what she 6 intended to do. 7 Q. Have you done an unjust enrichment 8 calculation for retailers? 9 A. I have not. 10 Q. So, you've done little more than 11 criticize what Dr. Conti did, but you've not 12 offered any other opinion about how to go about 13 it the right way, have you? 14 MS. KAPKE: Object to form. 15 Argumentative. 16 A. I have the critique in my report that 17 is summarized under Roman IX, and a section that 18 expands on that. I have not done a 19 quantification of unjust enrichment. 20 I have explained where I think there 21 are flaws in the overarching premise that 22 Dr. Conti puts forward, and the part that is 23 missing in my report is what she had said in her 24 deposition, where it seems that she thinks that</p>
<p style="text-align: right;">Page 235</p> <p>1 her deposition that she had opined that 2 additional costs would not be relevant to the 3 calculation, and in my opinion, additional costs 4 would be relevant to the calculation. 5 Q. And if -- if those costs were 6 identified and produced in -- in the model that 7 you're talking about, you could subtract those 8 and arrive at your own calculation for profits. 9 Couldn't you? 10 A. Not for the purposes of assessing 11 damages that accrue from individual plaintiffs 12 and any benefit that they im- -- brought to an 13 individual defendant, the portion of which would 14 be unjust for that defendant to keep. 15 I think tracing the costs through the 16 complex supply chain would be something that 17 could not be done with broad accounting level 18 data. 19 I have not seen what model Dr. Conti 20 purports to put forward to assess profits and 21 how to trace payments through from the -- 22 through the entire chain to assess what the 23 unjust portion of profits are for any part of 24 the chain or how they relate to specific</p>	<p style="text-align: right;">Page 237</p> <p>1 there are not relevant costs that would need to 2 be considered. 3 I think there are relevant costs that 4 would need to be considered, and it would be 5 very complex to be able to take them into 6 account appropriately to assess unjust 7 enrichment in the manner in which I understand 8 unjust enrichment damages need to be assessed. 9 Q. So you've assessed unjust enrichment 10 damages in the past. Have you not? 11 MS. KAPKE: Object to form. Vague. 12 Ambiguous. 13 A. I have worked on matters involving 14 unjust enrichment damages. I don't recall in a 15 class action setting having done so. 16 Q. Such models exist, don't they, in the 17 economic world? 18 A. Unjust enrichment damages models exist 19 in the economic world, yes. 20 MR. HONIK: Thank you. Those are all 21 the questions I have. 22 MS. KAPKE: I don't have redirect. 23 MR. HONIK: All right. That concludes 24 the deposition. Thank you, Dr. Stiroh.</p>

<div>Page 238</div> <div>1 THE WITNESS: Thank you. 2 THE VIDEOGRAPHER: The time right now 3 is 4:44 p.m. We are off the record. 4 (Time noted: 4:44 p.m.) 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24</div>	<div>Page 240</div> <div>1 C E R T I F I C A T E 2 3 S T A T E O F N E W Y O R K) 4) S s.: 5 C O U N T Y O F N E W Y O R K) 6 7 I JEFFREY BENZ, a Certified Realtime 8 Reporter, Registered Merit Reporter and Notary 9 Public within and for the State of New York, do 10 hereby certify: 11 That the witness whose examination is 12 hereinbefore set forth was duly sworn by me and 13 that this transcript of such examination is a true 14 record of the testimony given by such witness. 15 I further certify that I am not related to 16 any of the parties to this action by blood or 17 marriage and that I am in no way interested in the 18 outcome of this matter. 19 IN WITNESS WHEREOF, I have hereunto set my 20 hand this _____ of _____, 2022. 21 _____ 22 JEFFREY BENZ, CRR, RMR 23 24</div>
<div>Page 239</div> <div>1 2 A C K N O W L E D G E M E N T 3 S T A T E O F N E W Y O R K) 4) s s.: 5 C O U N T Y O F N E W Y O R K) 6 7 I, LAUREN J. STIROH, Ph.D., hereby certify, I 8 have read the transcript of my testimony taken 9 under oath in my deposition of March 25, 2022; 10 that the transcript is a true, complete and 11 correct record of what was asked, answered and 12 said during this deposition, and that the answers 13 on the record as given by me are true and correct. 14 15 _____ 16 LAUREN J. STIROH, Ph.D. 17 Subscribed and sworn to 18 before me on this _____ day 19 of _____, 2022 20 21 _____ 22 NOTARY PUBLIC 23 24</div>	

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Exhibit 212

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF NEW JERSEY
3 CAMDEN VICINAGE

- - -

4 IN RE: VALSARTAN, : MDL NO. 2875
5 LOSARTAN, AND :
6 IRBESARTAN PRODUCTS : CIVIL NO.
7 LIABILITY LITIGATION : 19-2875
8 : (RBK/JS)

9 :
10 THIS DOCUMENT APPLIES : HON. ROBERT
11 TO ALL CASES : B. KUGLER

12 - CONFIDENTIAL INFORMATION -
13 SUBJECT TO PROTECTIVE ORDER

14 - - -

15 March 10, 2022

16 - - -

17 Videotaped deposition of
18 URSINA R. TEITELBAUM, M.D., taken
19 pursuant to notice, was held via
20 in-person at Duane Morris, LLP, 30 South
21 17th Street, Philadelphia, Pennsylvania,
22 and also Zoom Videoconference for certain
23 parties, beginning at 9:18 a.m., EST, on
24 the above date, before Michelle L. Gray,
25 a Registered Professional Reporter,
26 Certified Shorthand Reporter, Certified
27 Realtime Reporter, and Notary Public.

- - -

28 GOLKOW LITIGATION SERVICES
29 877.370.3377 ph | 917.591.5672 fax
30 deps@golkow.com

<p style="text-align: right;">Page 2</p> <p>1 APPEARANCES: 2 3 LIEFF, CABRASER, HEIMANN & 4 BERNSTEIN, LLP 5 BY: RACHEL GEMAN, ESQ. (In person in Philadelphia) 6 250 Hudson Street, 8th Floor New York, New York 10013 (212) 355-9500 7 Rgeman@lchb.com 8 - and - 9 LIEFF, CABRASER, HEIMANN & 10 BERNSTEIN, LLP 11 BY: NICK W. LEE, ESQ. (Via Zoom) 12 275 Battery Street, 29th Floor San Francisco, California 94111 (415) 956-1000 13 Representing the Plaintiffs 14 MIGLIACCIO & RATHOD, LLP 15 BY: NICHOLAS MIGLIACCIO, ESQ. 16 BY: MARK PATRONELLA, ESQ. (Via Zoom) 17 412 H Street NE Suite 302 Washington, DC 20002 (202) 470-3520 Nmigliaccio@classlawdc.com 18 Representing the Plaintiffs 19 20 21 22 23 24</p>	<p style="text-align: right;">Page 4</p> <p>1 APPEARANCES: (Cont'd.) 2 3 PIETRAGALLO GORDON ALFANO BOSICK & 4 RASPANTI, LLP BY: JOHN B. ZAPPONE, ESQ. 5 BY: JASON M. REEFER, ESQ. (Via Zoom) 6 One Oxford Centre 38th Floor Pittsburgh, Pennsylvania 15219 (412) 263-1840 7 jbz@pietragallo.com 8 jmr@pietragallo.com 9 Representing the Defendant, Mylan Pharmaceuticals, Inc. 10 BARNES & THORNBURG, LLP 11 BY: MITCHELL CHARCHALIS, ESQ. (Via Zoom) 12 390 Madison Avenue, 12th Floor New York, New York 10017 (646) 746-2000 13 Mcharchalis@btlaw.com 14 Representing CVS Pharmacy, Inc., and Rite Aid Corporation 15 16 HILL WALLACK, LLP 17 BY: WILLIAM P. MURTHA, JR., ESQ. (Via Zoom) 18 21 Roszel Road Princeton, New Jersey 08543 (609) 452-1888 Wmurtha@hillwallack.com 19 Representing the Defendant, Hetero, USA, Inc., Hetero Labs 20 21 22 23 24</p>
<p style="text-align: right;">Page 3</p> <p>1 APPEARANCES: (Cont'd.) 2 3 DUANE MORRIS, LLP 4 BY: ROBERT KUM, ESQ. (In person in Philadelphia) 5 865 South Figueroa Street Suite 3100 Los Angeles, California 90017 (213) 689-7424 6 Rkum@duanemorris.com 7 Representing the Defendants, Zhejiang Huahai Pharmaceutical Co., Ltd., Princeton 8 Pharmaceutical Inc., Huahai U.S., Inc., and Solco Healthcare US, LLC 9 10 GREENBERG TRAURIG, LLP 11 BY: GLENN S. KERNER, ESQ. (In person in Philadelphia) 12 One Vanderbilt Avenue New York, New York 10017 (212) 801-9306 13 Kerner@gtlaw.com 14 - and - 15 GREENBERG TRAURIG, LLP 16 BY: STEVEN M. HARKINS, ESQ. (Via Zoom) 17 Terminus 200 3333 Piedmont Road NE Suite 2500 Atlanta, Georgia 30305 (678) 553-2312 18 Representing the Defendants, Teva Pharmaceutical Industries, Ltd., Teva 19 Pharmaceuticals USA, Inc., Actavis LLC, and Actavis Pharma, Inc. 20 21 22 23 24</p>	<p style="text-align: right;">Page 5</p> <p>1 APPEARANCES: (Cont'd.) 2 3 ALSO PRESENT: 4 5 VIDEOTAPE TECHNICIAN: 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24</p>

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- - -
I N D E X
- - -

Testimony of:

URSINA R. TEITELBAUM, M.D.

By Ms. Geman	10, 310
By Mr. Kerner	286

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D E P O S I T I O N S U P P O R T I N D E X
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Direction to Witness Not to Answer
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Request for Production of Documents
PAGE LINE
None.

Stipulations
PAGE LINE
None.

Questions Marked
PAGE LINE
None.

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- - -

THE VIDEOGRAPHER: We are now on the record.
 My name is Chris Ritona.
 I'm the videographer with Golkow Litigation Services.
 Today's date is March 10th, 2022, and the time is approximately 9:18 a.m.
 This video deposition is being held in Philadelphia, PA at Duane Morris, 30 South 17th Street, in the matter of Valsartan, Losartan, and Irbesartan Products Liability Litigation, MDL No. 2875.
 The deponent today is Dr. Ursina Teitelbaum.
 All counsel will be noted upon the stenographic record.
 The court reporter today is Michelle Gray, and she will now please swear in the witness.

- - -

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1 ... URSINA R. TEITELBAUM, M.D.,
2 having been first duly sworn, was
3 examined and testified as follows:
4 - - -
5 EXAMINATION
6 - - -
7 BY MS. GEMAN:
8 Q. Good morning.
9 A. Good morning.
10 Q. We met briefly off the
11 record, but my name is Rachel Geman.
12 Would you like to be
13 addressed as Dr. Teitelbaum? Am I saying
14 that right?
15 A. Yes, please.
16 Q. Okay. Could you please tell
17 me your business address?
18 A. Hospital of the University
19 of Pennsylvania, 3400 Convention Center
20 Boulevard, South Tower 10, Philadelphia,
21 Pennsylvania 19104.
22 Q. How many times have you
23 given testimony under oath?
24 A. I have given testimony under

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1 oath twice.
2 Q. And were they both
3 depositions?
4 A. Yes.
5 Q. Can you tell me when the
6 first one was?
7 A. It was 2007.
8 Q. And what was the nature of
9 that matter?
10 A. I was asked to speak about
11 the status of a patient's cancer, and it
12 was for the plaintiff.
13 Q. Was it a medical malpractice
14 suit?
15 A. Yes.
16 Q. Do you recall the name of
17 either the parties or the lawyers?
18 A. The lawyer's name was Rick
19 Levin. It was in Chicago.
20 Q. L-E-V-I-N?
21 A. Yes.
22 Q. And do you recall the name
23 of either party?
24 A. The defense was Northwestern

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1 Hospital.
2 Q. And do you recall what kind
3 of cancer the plaintiff had?
4 A. The patient had head and
5 neck cancer.
6 Q. And was the allegation that
7 the cancer was missed?
8 A. No.
9 Q. Can you tell me the
10 allegation?
11 A. The patient had locally
12 advanced head and neck cancer that was
13 being treated with curative intent. He
14 had undergone curative intent
15 chemoradiation and then had surgery.
16 He was in the hospital when
17 he had an airway event. And an
18 anesthesia code call was called overhead,
19 and it was called to the wrong building
20 in the hospital.
21 Q. Oh, dear. That sounds like
22 terrible facts.
23 And can you tell me about
24 the second time you were deposed?

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1 A. The second time was just
2 before the pandemic, so it was
3 January 2020.
4 Q. What was the nature of that
5 case?
6 A. I was testifying on behalf
7 of my patient.
8 Q. What is the name of your
9 patient?
10 A. I -- is that -- I think that
11 might be protected by HIPAA.
12 Q. Okay. Fair enough. Was
13 that a -- were you testifying in a
14 percipient or an expert capacity?
15 A. I was his physician. I'm
16 not sure what that legal definition is.
17 Q. Fair enough. Do you -- can
18 you tell me about the nature of the
19 lawsuit?
20 A. Yes. So the patient as a
21 young man in his 20s was working with
22 radioimmunoassays, so radioactive
23 elements. And I met him some years later
24 when he had a pancreatic cancer that I

<p style="text-align: right;">Page 14</p> <p>1 treated with curative intent.</p> <p>2 About two years after he was</p> <p>3 likely cured from the first cancer, he</p> <p>4 developed a cancer in his remnant</p> <p>5 pancreas, which is very unusual. And we</p> <p>6 looked back in his history to see, you</p> <p>7 know, multiple cancers at a young age is</p> <p>8 unusual.</p> <p>9 And he also had a melanoma,</p> <p>10 a testicular cancer, and multiple basal</p> <p>11 cancers. And they were all -- I don't</p> <p>12 know if I can do this, but they were on</p> <p>13 in a very limited field. And it turned</p> <p>14 out that was exactly the -- where the</p> <p>15 hood was to protect him from the</p> <p>16 radiation.</p> <p>17 And there had been some</p> <p>18 concerns about how the radioactive</p> <p>19 elements were handled in that company and</p> <p>20 how the hood was working.</p> <p>21 Q. Was he claiming the hood was</p> <p>22 defective?</p> <p>23 A. I don't think it was that</p> <p>24 specific. I think it was broader</p>	<p style="text-align: right;">Page 16</p> <p>1 Q. So --</p> <p>2 MR. KUM: Just to be -- just</p> <p>3 to be clear, she was the treater</p> <p>4 in the case. She wasn't an -- she</p> <p>5 wasn't an expert.</p> <p>6 MS. GEMAN: I understand.</p> <p>7 BY MS. GEMAN:</p> <p>8 Q. You were the --</p> <p>9 A. He was my patient.</p> <p>10 Q. I understand. Thank you.</p> <p>11 And do you recall the name</p> <p>12 of the lawyer who was with you at the</p> <p>13 deposition?</p> <p>14 A. Yes. His name is Mark</p> <p>15 Davies. I think it's also on that</p> <p>16 transcript.</p> <p>17 Q. Do you know what firm he is</p> <p>18 with?</p> <p>19 A. I think it's his own firm.</p> <p>20 Q. D-A-V-I-E-S?</p> <p>21 A. Yes.</p> <p>22 Q. Is he in Pennsylvania?</p> <p>23 A. Yes.</p> <p>24 Q. Philadelphia?</p>
<p style="text-align: right;">Page 15</p> <p>1 concerns about the management of the</p> <p>2 radioactive elements.</p> <p>3 Q. Do you know how that lawsuit</p> <p>4 resolved, if it did?</p> <p>5 A. They settled it.</p> <p>6 Q. Okay. And can you tell me</p> <p>7 the name of the defendant in that case?</p> <p>8 MR. KUM: So, Counsel, just</p> <p>9 to let you know, we did actually</p> <p>10 provide in the list of her</p> <p>11 materials the name of the lawsuit.</p> <p>12 MS. GEMAN: Oh.</p> <p>13 BY MS. GEMAN:</p> <p>14 Q. So was that suit David</p> <p>15 Boscher et al., versus Johnson & Johnson?</p> <p>16 A. Yes.</p> <p>17 Q. I see. And was that a -- do</p> <p>18 you know if that was a class action?</p> <p>19 A. It was not.</p> <p>20 Q. Okay. And that suit was</p> <p>21 resolved. I understand. And so you were</p> <p>22 testifying for the plaintiff in that</p> <p>23 case?</p> <p>24 A. Indeed.</p>	<p style="text-align: right;">Page 17</p> <p>1 A. Yes.</p> <p>2 Q. Well, you're doing a great</p> <p>3 job with the rules, but I will do the</p> <p>4 tedious lawyer thing and reacquaint you</p> <p>5 with the deposition rules regardless.</p> <p>6 Do you realize you're</p> <p>7 testifying today under a penalty of</p> <p>8 perjury?</p> <p>9 A. Of course.</p> <p>10 Q. And do you understand that</p> <p>11 I'm entitled to your best recollection?</p> <p>12 A. Yes.</p> <p>13 Q. If you don't understand a</p> <p>14 question I ask, can I ask you to ask me</p> <p>15 to clarify?</p> <p>16 A. With pleasure.</p> <p>17 Q. Thank you.</p> <p>18 And again, you're doing a</p> <p>19 great job with this, but if you could</p> <p>20 verbalize your answers rather than</p> <p>21 gesticulating or mm-hmm, unh-unh.</p> <p>22 Will you do that?</p> <p>23 A. Yes.</p> <p>24 Q. And do you understand that</p>

<p style="text-align: right;">Page 18</p> <p>1 I'm allowed to ask you to speculate to 2 matters within your knowledge? 3 A. Yes. 4 Q. So for example, I could ask 5 you to speculate the size of this table, 6 but I couldn't ask you to speculate the 7 size of my table at home. 8 Does that make sense? 9 A. Can you explain, give me 10 another example? 11 Q. Sure. 12 I could -- I wouldn't, but I 13 could ask you to speculate the collective 14 ages of the people in this room. But I 15 couldn't ask you to speculate the 16 collective ages of all my family members, 17 because of course you don't know them. 18 Is that fair? 19 A. Okay. 20 Q. Is there any reason you 21 can't testify today? 22 A. No. 23 Q. And if you need a break at 24 any time, please ask for it. I would</p>	<p style="text-align: right;">Page 20</p> <p>1 Q. Okay. And -- 2 MR. KUM: Yeah, so Doctor, 3 just as an admonition, you are 4 allowed to sort of generally 5 discuss the fact that we've met. 6 But I would ask you not to 7 directly provide information about 8 the substance of any of our 9 conversations. Okay? 10 THE WITNESS: Yes. 11 MR. KUM: Thank you. 12 BY MS. GEMAN: 13 Q. Had you previously worked 14 with RX Pro? 15 A. No. 16 Q. Had you heard of them before 17 they reached out to you? 18 A. No. 19 Q. Do you recall the name of 20 the person at RX Pro who reached out to 21 you? 22 A. His name is Patrick 23 O'Rourke. 24 Q. Oh, Patrick O'Rourke. Okay.</p>
<p style="text-align: right;">Page 19</p> <p>1 just ask that if there is a question 2 pending, that you answer it before the 3 break starts. 4 A. Yes. 5 Q. Who retained you in this 6 case? 7 A. I think there's a lot of 8 firms, so I'm not really sure how to 9 answer that. 10 Q. Fair enough. With which -- 11 with whom did you first speak about this 12 potential retention? 13 A. I was contacted by RX Pro 14 which I think is sort of a connecting -- 15 like a connector person that helps find 16 experts. 17 Q. Mm-hmm. 18 A. And I'm not sure why I said 19 yes, because I haven't in a long time. 20 But I said okay. 21 I had a 30-minute 22 conversation with Bob Kum where he mostly 23 asked questions about me. I think it 24 was --</p>	<p style="text-align: right;">Page 21</p> <p>1 And had you ever previously 2 met Mr. Kum before that phone call? 3 A. Never. 4 Q. When did RX Pro reach out to 5 you? 6 A. I think it was early 7 December 2021. 8 Q. And when was your -- and I'm 9 sorry. Did you say it was a phone call 10 with Mr. Kum or a meeting? 11 A. It was a phone call. 12 Q. Okay. When was that phone 13 call? 14 A. Probably within a week of 15 the outreach from Patrick O'Rourke. 16 Q. Is anybody at RX Pro working 17 with you on your report and opinions? 18 A. No. 19 Q. Is anybody working with you 20 on your report and opinions, like your 21 own staff or anything like that? 22 A. No. 23 Q. For which parties are you 24 providing your expert report?</p>

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1 A. I don't know all the names
2 of the firms.
3 Q. So I'm sorry. My
4 question -- my question wasn't clear.
5 Which -- you understand the
6 law firms are representing parties in the
7 litigation, correct?
8 A. Yes.
9 Q. So my question is, for which
10 parties, for which defendants, are you
11 providing your expert report?
12 A. I mean, it's for the
13 defense, but I don't know beyond that.
14 MR. KUM: And just for
15 clarification, Dr. Teitelbaum was
16 designated as an expert on behalf
17 of -- on behalf of all defendants.
18 MS. GEMAN: All defendants.
19 Okay.
20 BY MS. GEMAN:
21 Q. Have you ever done any
22 previous work for any of the defendants
23 in this litigation?
24 A. Never.

Page 23

1 Q. And who are the defendants
2 in this litigation?
3 A. I don't really know. I just
4 know the Duane Morris. I don't know all
5 the company names.
6 Q. Okay. Fair enough. Do you
7 know any of the company names that are
8 defendants in this litigation?
9 A. I don't think so.
10 Q. So is it -- can I fairly
11 infer that the reason that you're certain
12 that you have not worked for them before
13 is that you have not done any consulting
14 for companies?
15 A. I have never done any
16 consulting for companies.
17 Q. Okay. And can you tell me
18 the names, not the content of any
19 conversations, but the names of any
20 lawyers with whom you have met in
21 connection with your expert report and/or
22 prep for this deposition?
23 A. Yes. I just met Glen. But
24 he was on a Zoom once. It's kind of a

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1 lot of blobs with names. So forgive me.
2 Someone named Nick. I don't do great
3 with remembering the blob names. Someone
4 named Nilda.
5 There were more. But I
6 don't remember.
7 There was a woman in a Zoom
8 in Israel. And that's kind of it.
9 Q. Fair enough. Do you know,
10 were those individuals all attorneys?
11 A. I don't know.
12 Q. Have you spoken with anyone
13 about this deposition other than counsel?
14 A. Absolutely not.
15 Q. Have you spoken with anyone
16 about your expert report other than
17 counsel?
18 A. No.
19 Q. And on the subject of
20 deposition prep, how much time did you
21 spend preparing for this deposition?
22 A. I'm not really sure. Some
23 hours.
24 Q. Could you give me an order

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1 of magnitude?
2 A. Less than ten.
3 Q. And were -- would you say it
4 was seven to nine?
5 A. Five to eight.
6 Q. Five to eight. And were
7 those five to eight hours all with
8 counsel?
9 A. Is counsel attorneys?
10 Q. Yes.
11 A. Yes.
12 Q. Did you do any preparation
13 on your own?
14 A. For what?
15 Q. For this deposition.
16 A. I don't know what that
17 means. Can you explain?
18 Q. Sure.
19 Did you do any reading or
20 research or revisit any materials?
21 A. I studied my expert letter,
22 I studied Dr. Kaplan's expert letter, and
23 I reviewed Dr. Kaplan's deposition.
24 Q. Have you reviewed any

<p>Page 26</p> <p>1 depositions in this matter other than 2 Dr. Kaplan's? 3 A. I haven't. 4 Q. Your list of materials 5 reviewed did not mention Dr. Kaplan, but 6 obviously you reviewed his materials, 7 correct? 8 A. Yes. I think that was the 9 premise of my mission. 10 Q. Fair enough. Did you review 11 Dr. Song's report? 12 A. I did not. 13 Q. Are you -- and so your 14 testimony is limited to responding to 15 Dr. Kaplan; is that correct? 16 A. That is what I was asked to 17 do. And that's what it's limited to. 18 Q. All right. And your 19 opinions are limited to responding to 20 Dr. Kaplan; is that correct? 21 A. I was specifically asked to 22 offer my opinion on Dr. Kaplan's medical 23 monitoring plan. 24 Q. And are you offering any</p> <p>Page 27</p> <p>1 opinions about whether NDMA or NDEA are 2 carcinogens? 3 A. I am not a causative expert. 4 Q. And regardless of that, 5 which I appreciate, are you offering any 6 opinions about whether those substances 7 are causation -- are carcinogens? 8 A. I am not. It's really not 9 pertinent to my opinion. 10 Q. Are you offering -- 11 MS. GEMAN: Oh, is this the 12 phone in here? 13 (Whereupon, a discussion was 14 held off the stenographic record.) 15 BY MS. GEMAN: 16 Q. Are you offering any 17 opinions, Doctor, about whether NDMA or 18 NDEA in the levels that were present in 19 the contaminated valsartan in this case 20 caused significantly increased risk of 21 cancer to any person? 22 A. I am not. 23 MR. KUM: I'm just going to 24 object. Outside the scope.</p>	<p>Page 28</p> <p>1 Dr. Teitelbaum, if you can 2 just pause for just a second and 3 let me interject an objection. 4 MS. GEMAN: Thank you. 5 BY MS. GEMAN: 6 Q. Are you offering any 7 opinions about the medical monitoring 8 class definition in this case? 9 MR. KUM: Objection. Vague 10 and ambiguous. Outside the scope. 11 THE WITNESS: I don't 12 understand your question. 13 BY MS. GEMAN: 14 Q. Sure. Are you offering -- 15 strike that. 16 You reviewed the amended 17 complaint brought by the medical 18 monitoring plaintiffs, correct? 19 A. I don't think I've seen 20 that. 21 Q. If it was listed in your 22 materials reviewed, would that have been 23 a mistake? 24 A. Is that -- I don't know what</p> <p>Page 29</p> <p>1 that means. Is that that request for -- 2 that deposition request? 3 MR. KUM: So I don't think 4 she understands what you mean by a 5 complaint. You might want to -- 6 BY MS. GEMAN: 7 Q. Did you review the document 8 that set forth the allegations that the 9 medical monitoring plaintiffs brought 10 against the defendants? 11 A. I think that's that form? 12 Can you show it to me, Bob? I know what 13 it looks like. I'm not that familiar 14 with the terminology. I apologize. 15 Q. Fair enough. So is it fair 16 to say that you're not offering any 17 opinion about how the plaintiffs have 18 defined who should be entitled to medical 19 monitoring in this case? 20 MR. KUM: Objection. Vague 21 and ambiguous. 22 THE WITNESS: Can you 23 explain again? 24 BY MS. GEMAN:</p>
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<p style="text-align: right;">Page 30</p> <p>1 Q. Sure.</p> <p>2 A. I'm not a lawyer.</p> <p>3 Q. Fair. No, no, I understand.</p> <p>4 And I'm definitely not asking for legal</p> <p>5 opinions.</p> <p>6 I am asking, however, if you</p> <p>7 have an opinion about how the plaintiffs</p> <p>8 have defined the threshold eligibility to</p> <p>9 be entitled to monitoring.</p> <p>10 MR. KUM: Objection.</p> <p>11 Outside the scope.</p> <p>12 BY MS. GEMAN:</p> <p>13 Q. You can answer.</p> <p>14 A. Yeah, I just don't still --</p> <p>15 I still don't understand. I'm not -- I'm</p> <p>16 not trying to be dense. I just don't</p> <p>17 understand.</p> <p>18 Q. No, not at all. What is</p> <p>19 your understanding about, broadly</p> <p>20 speaking, who plaintiffs claim should be</p> <p>21 entitled to medical monitoring?</p> <p>22 A. I think it's patients that</p> <p>23 took VCDs with the impurity NDMA and NDEA</p> <p>24 within a certain time period.</p>	<p style="text-align: right;">Page 32</p> <p>1 opinions here about the economics of</p> <p>2 medical monitoring?</p> <p>3 A. No.</p> <p>4 Q. You're not a public health</p> <p>5 expert, correct?</p> <p>6 MR. KUM: Objection. Vague</p> <p>7 and ambiguous.</p> <p>8 THE WITNESS: I'm interested</p> <p>9 in public health. It's an</p> <p>10 important part of my practice.</p> <p>11 BY MS. GEMAN:</p> <p>12 Q. Do you consider yourself</p> <p>13 qualified to render expert opinions about</p> <p>14 public health topics?</p> <p>15 A. It depends on the topic.</p> <p>16 I'm happy to opine if I am asked the</p> <p>17 right question.</p> <p>18 Q. Do you consider your opinion</p> <p>19 here to be related to public health?</p> <p>20 A. I consider my opinion here</p> <p>21 to be related to the medical monitoring</p> <p>22 protocol put forward by Dr. Kaplan.</p> <p>23 Q. And do you consider that to</p> <p>24 be an aspect of public health?</p>
<p style="text-align: right;">Page 31</p> <p>1 Q. Also, sorry, what is</p> <p>2 curative intent?</p> <p>3 A. Oh, that's a great question.</p> <p>4 Oncologists are always delighted to have</p> <p>5 that opportunity.</p> <p>6 Broadly speaking, the only</p> <p>7 way to cure a solid a tumor is surgery.</p> <p>8 And so if a patient is eligible for</p> <p>9 surgery, we may add some chemotherapy or</p> <p>10 radiation. But if a patient is eligible</p> <p>11 for surgery, we are treating them with</p> <p>12 the goal of cure.</p> <p>13 Q. And do you define cure as</p> <p>14 being cancer free for five years?</p> <p>15 A. It depends on the cancer.</p> <p>16 Q. Is it always a temporal</p> <p>17 definition, as in cancer free for X time?</p> <p>18 A. Different cancers have</p> <p>19 different ranges of time. Some have a</p> <p>20 longer tail than others.</p> <p>21 Q. But it's always defined by a</p> <p>22 temporal period of being cancer free?</p> <p>23 A. Yes. Mm-hmm.</p> <p>24 Q. And are you offering any</p>	<p style="text-align: right;">Page 33</p> <p>1 A. Can you ask that again?</p> <p>2 MR. KUM: Objection. Vague</p> <p>3 and ambiguous.</p> <p>4 BY MS. GEMAN:</p> <p>5 Q. Do you consider that to be a</p> <p>6 public health opinion?</p> <p>7 MR. KUM: Same objections.</p> <p>8 THE WITNESS: Yeah, the</p> <p>9 opinion about his medical</p> <p>10 monitoring protocol. Let me think</p> <p>11 about that.</p> <p>12 I would say cancer screening</p> <p>13 is within the domain of public</p> <p>14 health, although it's also within</p> <p>15 the domain of other --</p> <p>16 biostatistics, health outcomes,</p> <p>17 you know.</p> <p>18 So I'm really directing my</p> <p>19 opinion to the screening protocol</p> <p>20 put forward. I don't really know</p> <p>21 how to answer your question within</p> <p>22 that context.</p> <p>23 BY MS. GEMAN:</p> <p>24 Q. Do you consider yourself an</p>

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1 expert in biostatistics?
2 A. I use and rely on
3 biostatistics in my clinical practice of
4 20 years. We're certainly taught
5 biostatistics in medical school. And
6 ongoing, it's important in fellowship and
7 I rely on it and refer to it in my
8 practice.
9 Q. Do you consider yourself an
10 expert in biostatistics?
11 MR. KUM: Objection. Calls
12 for a legal conclusion.
13 THE WITNESS: Again, I
14 certainly use biostatistics in my
15 practice.
16 BY MS. GEMAN:
17 Q. Do you consider yourself an
18 expert in biostatistics?
19 MR. KUM: Same objection.
20 Calls for a legal conclusion.
21 BY MS. GEMAN:
22 Q. You can answer, unless your
23 counsel instructs you not to answer.
24 A. I know. I did answer.

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1 So...
2 Q. So, my question is, to which
3 I have not gotten an answers do you
4 consider yourself an expert in
5 biostatistics?
6 MR. KUM: Same objections.
7 You can answer again,
8 Doctor.
9 THE WITNESS: Yeah, I rely
10 on biostatistics in my practice.
11 I have been in multiple lectures.
12 It's an important part of clinical
13 practice. I don't know how to
14 answer you more specifically.
15 The question is broad, even
16 though it's just a few words.
17 BY MS. GEMAN:
18 Q. Would you consider yourself
19 qualified to present yourself to a judge
20 and jury as an expert in biostatistics?
21 MR. KUM: Objection. Calls
22 for a legal conclusion.
23 If you understand.
24 THE WITNESS: I would just

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1 tell them I use it. I don't have
2 a degree in it. But I rely on it,
3 and I appreciate it, and I use it
4 in my daily practice.
5 BY MS. GEMAN:
6 Q. I mean, I have a lot of
7 friends who are biostatisticians. I rely
8 on it when I read the New York Times and
9 so on. Would you consider me an expert
10 in biostatistics?
11 MR. KUM: Objection. Vague.
12 Ambiguous.
13 THE WITNESS: I don't really
14 need to answer that question.
15 MR. KUM: Doctor, go ahead
16 and answer.
17 THE WITNESS: Okay. I --
18 MR. KUM: To the extent you
19 can, if you understand the
20 question.
21 THE WITNESS: I don't -- I
22 don't know your depth of
23 knowledge. I don't know how you
24 would present yourself. I don't

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1 know if you use it in your daily
2 practice.
3 I rely on statistics to
4 guide my patients. I use them
5 every day. I don't have a
6 master's or a Ph.D. in
7 biostatistics. But I use and rely
8 on biostatistics every day that
9 I'm in clinic caring for patients.
10 BY MS. GEMAN:
11 Q. Have you ever taught public
12 health or biostatistics?
13 A. I have not.
14 Q. Have you ever published a
15 paper about -- in a public health
16 journal?
17 A. I don't think so.
18 Q. Have you ever published a
19 paper in a biostatistics journal?
20 A. I don't think so.
21 Q. Okay. And are you offering
22 any opinions about the feasibility of
23 medical monitoring as distinct from
24 whether it's, in your view, clinically

<p>Page 38</p> <p>1 warranted?</p> <p>2 MR. KUM: Objection. Vague</p> <p>3 and ambiguous. If you understand</p> <p>4 the distinction.</p> <p>5 THE WITNESS: Yes. Only in</p> <p>6 that if the patients being offered</p> <p>7 this very intensive medical</p> <p>8 monitoring protocol are frail or</p> <p>9 very sick or -- you know, for</p> <p>10 example, repeat upper and lower</p> <p>11 endoscopy, requires anesthesia and</p> <p>12 cardiology clearance. If they</p> <p>13 have heart conditions that</p> <p>14 preclude it, then it isn't</p> <p>15 feasible. So just to that extent.</p> <p>16 BY MS. GEMAN:</p> <p>17 Q. Is it your understanding</p> <p>18 that a patient would be required to avail</p> <p>19 him or herself of the services of the</p> <p>20 medical monitoring program that has been</p> <p>21 proposed?</p> <p>22 A. It didn't say that in</p> <p>23 Dr. Kaplan's letter. I worry that if</p> <p>24 they know these are the recommended</p>	<p>Page 40</p> <p>1 MR. KUM: Objection. Vague</p> <p>2 and ambiguous. Calls for a legal</p> <p>3 conclusion.</p> <p>4 THE WITNESS: I haven't seen</p> <p>5 the "mandatory" word as I recall,</p> <p>6 but I don't know that it isn't.</p> <p>7 It's being offered. The</p> <p>8 idea is to offer it, and I think</p> <p>9 that alone would engender a lot of</p> <p>10 anxiety and fear and potentially</p> <p>11 pressure because of the fear of</p> <p>12 cancer.</p> <p>13 BY MS. GEMAN:</p> <p>14 Q. Have you purported to study</p> <p>15 the delta between the baseline fear that</p> <p>16 these class members already have and any</p> <p>17 additional fear engendered by the</p> <p>18 program?</p> <p>19 A. In my expert report, I did</p> <p>20 comment on anxiety and stress associated</p> <p>21 with cancer testing. And you know,</p> <p>22 patients that are told they are at higher</p> <p>23 risk, have more stress about it.</p> <p>24 I'll also say that the more</p>
<p>Page 39</p> <p>1 tests, because the fear of cancer is so</p> <p>2 pervasive, that they would feel a</p> <p>3 compulsion to try and do them.</p> <p>4 Q. Putting aside your worry,</p> <p>5 you understand that Dr. Kaplan is not</p> <p>6 proposing a mandatory program, correct?</p> <p>7 MR. KUM: Objection. Vague</p> <p>8 and ambiguous. Calls for a legal</p> <p>9 conclusion.</p> <p>10 THE WITNESS: He put forward</p> <p>11 a recommended protocol.</p> <p>12 I don't know. In the letter</p> <p>13 he didn't say whether or not it</p> <p>14 was mandatory.</p> <p>15 I was certainly happy during</p> <p>16 his deposition to go to the basic</p> <p>17 principle of medicine, the art of</p> <p>18 medicine, that it's a personalized</p> <p>19 approach between the patient and</p> <p>20 their physician. So I was very</p> <p>21 happy to read that.</p> <p>22 BY MS. GEMAN:</p> <p>23 Q. Do you understand that the</p> <p>24 program is not mandatory?</p>	<p>Page 41</p> <p>1 you test someone, the frequency, the more</p> <p>2 opportunity there is for false diagnoses.</p> <p>3 And just having a false positive and just</p> <p>4 being told that you might have cancer and</p> <p>5 then going through the workup, even if</p> <p>6 you're negative, it creates fear with</p> <p>7 every subsequent test.</p> <p>8 I see that in our own</p> <p>9 practice. We used to use a lot more</p> <p>10 imaging to track cancers. We were</p> <p>11 following them in surveillance.</p> <p>12 And there's actually a whole</p> <p>13 literature now around what we call</p> <p>14 "scanxiety" where the very act of testing</p> <p>15 for cancer causes anxiety.</p> <p>16 MS. GEMAN: So I'm going to</p> <p>17 be ask for that to be struck as</p> <p>18 nonresponsive.</p> <p>19 BY MS. GEMAN:</p> <p>20 Q. My question is, have you</p> <p>21 purported to study the delta between the</p> <p>22 baseline fear that these class members</p> <p>23 already have and any additional fear</p> <p>24 engendered by the program?</p>

<p style="text-align: right;">Page 42</p> <p>1 MR. KUM: Asked and 2 answered. 3 You can answer again. 4 THE WITNESS: In terms of 5 study, I have not written or 6 published in it. But I have 7 certainly experienced it in my 8 years of practice. 9 BY MS. GEMAN: 10 Q. Have you made any attempt to 11 gauge the baseline level of anxiety these 12 class members already have by dint of 13 having consumed contaminated valsartan? 14 MR. KUM: Objection. 15 Assumes facts not in evidence. 16 Vague and ambiguous. You can 17 answer. 18 THE WITNESS: I have not. I 19 am not aware of their fear level. 20 BY MS. GEMAN: 21 Q. Do you deny that there is a 22 baseline level of anxiety? Or rather -- 23 I can rephrase the question. 24 Do you have any opinions</p>	<p style="text-align: right;">Page 44</p> <p>1 that the FDA recognized their 2 cardiovascular risk and said don't 3 stop it, keep taking it until you 4 talk to your doctor. 5 BY MS. GEMAN: 6 Q. What do you mean by notable? 7 A. Well, if -- you know, 8 gauging risk, I think the FDA recognized 9 that the cardiovascular risk was great 10 and that stopping that medication would 11 cause harm. 12 Q. Did you learn about the 13 recall in real time when it happened? 14 A. No. 15 Q. And I think you said this in 16 your objections to the subpoena, but you 17 have not written or -- you have not 18 written about valsartan or blood pressure 19 medications, correct? 20 A. I have not. 21 Q. Have you talked about 22 valsartan with your patients? 23 A. Not for many years. Early 24 in my career, I did work in primary care.</p>
<p style="text-align: right;">Page 43</p> <p>1 about the baseline level of anxiety 2 experienced by the proposed class 3 members? 4 MR. KUM: Objection. Calls 5 for speculation, assumes facts not 6 in evidence. 7 THE WITNESS: Is that a 8 speculate question? 9 MR. KUM: Doctor, I'm 10 just -- I'm asserting an objection 11 on the record. 12 THE WITNESS: Okay. 13 MR. KUM: To the extent that 14 you understand her question, you 15 can answer. 16 THE WITNESS: You know, it's 17 interesting. Heart disease is the 18 number one cause of death in the 19 U.S. But my patients are more 20 afraid of cancer. 21 I can imagine that the FDA 22 report of a concern for an 23 impurity was very anxiety 24 provoking. I think it's notable</p>	<p style="text-align: right;">Page 45</p> <p>1 And I -- normally a patient came to me on 2 valsartan after a critical event, usually 3 in a hospital, myocardial infarction, new 4 diagnosis of heart failure or diabetes 5 affecting their kidney function, which 6 are indications. 7 The only instance in which I 8 wrote it primarily was if a patient was 9 intolerant of an ACE inhibitor due to 10 cough. 11 I currently do not, and have 12 instructed my office, to not renew 13 patients' medications that aren't 14 directly related to their cancer care. 15 Q. So they should go to 16 their -- another specialist or primary 17 care doctor? 18 A. You know, our patients see 19 us every week or two weeks. We write a 20 lot of prescriptions. It's very natural 21 that they would ask. But it's not the 22 area that I'm focusing now, and I think 23 it would be a disservice, and I also 24 would not want to delay the time that</p>

<p style="text-align: right;">Page 46</p> <p>1 they would then see their internist, 2 family medicine doctor, or cardiologist. 3 So it is not my practice now to write or 4 renew valsartan-containing drugs. 5 Q. Have you prescribed 6 valsartan in the last ten years? 7 A. I have not prescribed 8 valsartan in the past 18 years. 9 Q. Okay. What happened 10 18 years ago? 11 A. I moved -- I was in my 12 geriatrics clinics, which was a form of 13 primary care. And then I moved 14 exclusively to oncology clinics. I'm 15 board-certified in internal medicine, 16 geriatrics, medical oncology, and 17 palliative care. 18 So I've had a lot of 19 training. But currently, I'm working in 20 oncology clinics, subspecializing in 21 gastrointestinal malignancies. 22 Q. Do you only treat or 23 exclusively treat GI cancers? 24 A. So I largely -- I'm one of</p>	<p style="text-align: right;">Page 48</p> <p>1 A. Again, it's in the construct 2 of being an attending in the hospital and 3 in the clinic. 4 In my clinic, I only get -- 5 accept referrals for gastrointestinal 6 malignancies. But again, I like the 7 workup and teaching opportunities for the 8 fellows with cancers of unknown primary, 9 which sometimes turn out to be breast or 10 lung. So that's why I'm explaining my 11 answer. 12 And on the inpatient side we 13 don't have the luxury of just treating GI 14 cancers. We accept all of the inpatients 15 of the entire practice. 16 Q. So if you've said publicly 17 that you only do GI cancers, was that a 18 slight exaggeration for marketing 19 purposes? 20 A. That's the -- if you look at 21 the list of cancers accepted on my 22 profile, it's all GI cancers. And 23 cancers of unknown primary is listed on 24 that. That is my outpatient clinic.</p>
<p style="text-align: right;">Page 47</p> <p>1 the few in our practice that will see 2 cancers of unknown primary. So that 3 could be any range of cancers. 4 And on the inpatient side, 5 we are required to do a fair amount of 6 inpatient. I attend on the solid tumor 7 services, which is every type of cancer. 8 And actually, I also attend on the bone 9 marrow transplant service. 10 Q. Was there a time in your 11 career when you only worked on GI 12 cancers? 13 A. I've been doing this since I 14 came to Penn. That's, you know, in the 15 hospital, you see all patients. I'm 16 trained to see all patients. And I have 17 chosen to subspecialize, which is an 18 opportunity in academic medicine. And 19 that way you can have a more narrower 20 area of disease expertise. 21 Q. So I'm sorry. I'm not sure 22 I know the answer to the question. Was 23 there a time in your career when you only 24 worked on GI cancers?</p>	<p style="text-align: right;">Page 49</p> <p>1 We all have to do service 2 time. It's two weeks or four weeks a 3 year. So I just wanted to be very 4 truthful that I am exposed to other 5 cancers. 6 But in my clinic, I see 7 gastrointestinal cancers and the rare 8 cancer of unknown primary. 9 Q. So your public statement 10 that you only treat GI cancers is not 11 quite correct? 12 A. It's within -- that's my 13 specialty interest. All of us see 14 cancers that are thought to be GI and 15 turn out to be something else. So I 16 think within that, it is still my 17 intention. 18 Q. So why did you say publicly 19 you only treat GI cancers, if that is not 20 true? 21 MR. KUM: Objection. Vague 22 and ambiguous. Assumes facts not 23 in evidence. 24 If you know what she's</p>

<p style="text-align: right;">Page 50</p> <p>1 referring to.</p> <p>2 THE WITNESS: I'm not</p> <p>3 understanding your term</p> <p>4 "publicly."</p> <p>5 BY MS. GEMAN:</p> <p>6 Q. Did you put out a YouTube</p> <p>7 video available for anyone to see in</p> <p>8 which you said that you only treat GI</p> <p>9 cancers?</p> <p>10 A. The intent of my practice is</p> <p>11 GI cancers.</p> <p>12 I generally, if -- maybe</p> <p>13 there are six or seven cancers of unknown</p> <p>14 primary, which is also listed on my</p> <p>15 public profile.</p> <p>16 I tend to take the ones that</p> <p>17 have cancer below the diaphragm, assuming</p> <p>18 that they will be GI. But that's, you</p> <p>19 know, just -- that was a -- they asked me</p> <p>20 to talk about my GI practice. That is my</p> <p>21 area of expertise.</p> <p>22 Q. Did they ask you to say that</p> <p>23 you only treat GI cancers?</p> <p>24 A. I don't remember if they did</p>	<p style="text-align: right;">Page 52</p> <p>1 cancers?</p> <p>2 A. I do not treat blood cancers</p> <p>3 in the outpatient setting.</p> <p>4 Q. Do you treat them anywhere?</p> <p>5 A. I -- two years ago I</p> <p>6 attended on the inpatient transplant</p> <p>7 service. I haven't attended there for</p> <p>8 two years.</p> <p>9 Q. And previous to that</p> <p>10 attendance on the inpatient transplant</p> <p>11 service, when had been the last time that</p> <p>12 you had treated blood cancers?</p> <p>13 A. Fellowship.</p> <p>14 Q. Okay. Like 20 years ago?</p> <p>15 A. More.</p> <p>16 Q. More. How long was that</p> <p>17 attendance to which you just referred on</p> <p>18 the inpatient transplant service?</p> <p>19 A. It's two weeks every year.</p> <p>20 Q. So in the last -- so in the</p> <p>21 last greater than 20 years, have you just</p> <p>22 spent two weeks treating blood cancers,</p> <p>23 or do you mean two weeks every year? I'm</p> <p>24 sorry if I misunderstood.</p>
<p style="text-align: right;">Page 51</p> <p>1 or not. I think it was just a</p> <p>2 promotional video on behalf of the</p> <p>3 gastrointestinal program. My clinic is</p> <p>4 called the gastrointestinal malignancy</p> <p>5 clinic, and that is within the group that</p> <p>6 I practice.</p> <p>7 Q. Do you think it would be</p> <p>8 more truthful to amend that video?</p> <p>9 MR. KUM: Objection.</p> <p>10 Argumentative.</p> <p>11 THE WITNESS: I intend to</p> <p>12 treat GI cancers. I accept the</p> <p>13 cancers of unknown primary that</p> <p>14 are below the diaphragm.</p> <p>15 If they turn out to have a</p> <p>16 breast cancer, I usually pass them</p> <p>17 on to my breast cancer colleague.</p> <p>18 Not every oncologist is willing to</p> <p>19 take a cancer without a firm</p> <p>20 diagnosis.</p> <p>21 I am willing, for the</p> <p>22 interest of the patient.</p> <p>23 BY MS. GEMAN:</p> <p>24 Q. Do you currently treat blood</p>	<p style="text-align: right;">Page 53</p> <p>1 A. Oh, I -- the -- let's see.</p> <p>2 I came to Penn in 2007. I stopped doing</p> <p>3 it as a courtesy to the division. It was</p> <p>4 actually before the pandemic. So</p> <p>5 probably 2019.</p> <p>6 There are a lot of services</p> <p>7 that are tough to get coverage for. So</p> <p>8 it was a courtesy to the division.</p> <p>9 Q. So I don't think that was</p> <p>10 responsive.</p> <p>11 So do you, in the last</p> <p>12 20 years plus, other than that two-week</p> <p>13 period to which you referred, how much</p> <p>14 time have you spent treating blood</p> <p>15 cancers?</p> <p>16 A. None since fellowship.</p> <p>17 Q. Okay. So it's been two</p> <p>18 weeks in the last 20 years?</p> <p>19 A. But for 12 years in a row I</p> <p>20 did two weeks.</p> <p>21 Q. That's what I was asking.</p> <p>22 A. Yes.</p> <p>23 Q. Okay. You've had 24 weeks?</p> <p>24 A. Yes. Remember, these are</p>

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1 patients going through transplant. Our
2 role is largely to manage infection.
3 Q. Mm-hmm. As opposed to
4 treating the primary?
5 A. It's managing their
6 hospitalization.
7 Q. As opposed to treating the
8 primary cancer?
9 MR. KUM: Objection. Vague
10 and ambiguous.
11 If you understand the
12 distinction.
13 THE WITNESS: Yeah. Yeah,
14 I'm taking care of a patient,
15 getting a treatment plan in the
16 hospital. And my -- you know,
17 managing their infections, if they
18 get infection or symptoms.
19 BY MS. GEMAN:
20 Q. Do you devise their cancer
21 treatment plans?
22 A. I do not.
23 Q. Do you treat lung cancer?
24 A. Excuse me?

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1 Q. I'm sorry. Do you treat
2 lung cancer?
3 A. I do not.
4 Q. Do you treat liver cancer?
5 A. I do.
6 Q. You do. Okay. And liver
7 cancer can be cured or curable if caught
8 early; is that correct?
9 MR. KUM: Objection. Vague
10 and ambiguous. Incomplete
11 hypothetical.
12 THE WITNESS: It all depends
13 on if a surgery is possible.
14 BY MS. GEMAN:
15 Q. And if it is, liver cancer
16 can be cured if caught early; is that
17 correct?
18 A. Yes, or transplant.
19 Q. And you do treat pancreatic
20 cancer; is that correct?
21 A. About 70 percent of my
22 practice is pancreas cancer.
23 Q. Oh, wow. And how would you
24 divide the other 30?

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1 A. So 10 percent
2 esophagogastric. I'm more interested in
3 upper GI intestinal malignancies,
4 although I attend all -- we have multiple
5 tumor -- interdisciplinary tumor board.
6 We have a tumor board for every disease
7 site. So I also care for patients with
8 colorectal cancer. I would lump small
9 bowel cancer into colorectal cancer, and
10 neuroendocrine tumors.
11 Q. So of that remaining
12 20 percent, how much would you say is --
13 A. That's why I was trying --
14 three of them, 10, 10, and 10, is roughly
15 what I would say.
16 Q. So 10 for esophageal?
17 A. Esophagogastric.
18 Q. Mm-hmm. I see.
19 A. And 10 or bowel cancer,
20 large and small, and 10 percent for
21 neuroendocrine tumor.
22 Q. And forgive my ignorance.
23 Do you embed prostate cancer into
24 neuroendocrine?

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1 A. Oh, no.
2 Q. No? Okay.
3 A. That's a separate -- that's
4 GU, gastro-urinary.
5 Q. Do you treat gastro-urinary
6 cancer?
7 A. No.
8 Q. So that means that you don't
9 treat prostate or bladder; is that
10 correct?
11 A. Or kidney.
12 Q. Or kidney. And what is an
13 example of a neuroendocrine cancer?
14 A. Mm-hmm. So when you think
15 neuroendocrine, you think Steve jobs. He
16 had a pancreas neuroendocrine tumor.
17 Anything -- any
18 neuroendocrine tumor that doesn't arise
19 from the pancreas is called carcinoid
20 tumor.
21 Q. And can that happen in any
22 body part?
23 A. There is a separate entity
24 in the lung, but generally it's in the

<p>Page 58</p> <p>1 pancreas, small bowel. It can arise in 2 the rectum. Those are the normal 3 locations. 4 Q. And you consider those 5 distinct from small bowel and colorectal 6 cancers? 7 A. Completely different cell 8 type. Completely different treatment 9 regimen. Every cancer has its own 10 prescription. 11 MS. GEMAN: The reason that 12 you see me glancing at the time is 13 because I'm staring at something 14 that says 7:05 a.m., which might 15 be on Pacific time. 16 MR. KUM: That's in honor of 17 me being a west coast attorney. 18 MS. GEMAN: I'm sorry? 19 MR. KUM: It's in honor of 20 me being a California attorney. 21 MS. GEMAN: I understand. 22 Everything has to be three hours 23 earlier. 24 BY MS. GEMAN:</p>	<p>Page 60</p> <p>1 patients are not always as adherent as 2 you think. In fact, if you miss a week 3 out of a month, that's still considered 4 adherent. That's 80 percent. 5 The average is 50 percent in 6 the literature. When I have my -- 7 particularly my older patients, I have 8 them bring in a bag of their medicines so 9 I can actually look through and do a pill 10 count to try and help figure out how much 11 of them they're taking. 12 And of course, sometimes 13 there's issue with affording medications 14 or tolerating medications. A lot of 15 times I find patients stop the medication 16 without telling their physician. 17 So I think that's how -- 18 I -- assuming they're taking them, but we 19 all know that there's some variability 20 there. 21 Q. Are you offering any 22 opinions about the adherence of these 23 class members? 24 A. I have no idea what their</p>
<p>Page 59</p> <p>1 Q. Okay. Thank you. That's 2 very -- that's very helpful. 3 Do your opinions in this 4 case apply to the general population or 5 to the medical monitoring class? 6 MR. KUM: Objection. Vague 7 and ambiguous as to which opinions 8 you're referring to. 9 THE WITNESS: I specifically 10 directed my opinion to the medical 11 monitoring program put forward by 12 Dr. Kaplan for this, the 13 valsartan-containing drug 14 population that may have been 15 exposed to the impurities, NDMA 16 and NDEA. 17 BY MS. GEMAN: 18 Q. And is it your understanding 19 that they may have been exposed or that 20 they were exposed? 21 A. I only bring it up because 22 of the issue of adherence that I did 23 mention in my expert letter. And having 24 cared for patients with -- you know,</p>	<p>Page 61</p> <p>1 adherence was. I'm just speaking to a 2 general phenomenon that's well described 3 in the literature. 4 Q. Did you study the adherence 5 of the named plaintiffs? 6 MR. KUM: Objection. 7 Outside the scope. You can 8 answer. 9 THE WITNESS: I don't know 10 who they are. I don't know if 11 it's been assessed. I did not 12 study it. 13 BY MS. GEMAN: 14 Q. So you're offering no -- 15 just to be clear, you're offering no 16 expert opinions about the adherence of 17 the class here; is that correct? 18 A. I'm speaking to the general 19 study of adherence in patients taking 20 medications. It is not specific to these 21 patients or to these drugs. 22 Q. And you're offering no 23 expert opinions on that subject here, 24 correct?</p>

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1 MR. KUM: I'm going to
2 object. Other than to what she's
3 just testified to.
4 MS. GEMAN: You can't do
5 speaking objections.
6 MR. KUM: Objection. Asked
7 and answered.
8 You can answer again.
9 THE WITNESS: I addressed
10 the general concern about
11 adherence to medications in
12 general terms in my letter.
13 BY MS. GEMAN:
14 Q. But again, I'm entitled to
15 know if you are claiming to offer expert
16 opinions on the adherence of the class
17 here.
18 A. I have no idea what
19 medicines they did or did not take.
20 Q. Okay.
21 A. I don't know about any
22 individual patients.
23 Q. And as a threshold, I think
24 it's -- am I correct to think that Dr. --

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1 that your opinion is that Dr. Kaplan's
2 protocol, in your view, should not be
3 applied to the general population; is
4 that correct?
5 A. The general VCD-taking
6 population?
7 Q. No, no, no. The general
8 population?
9 MR. KUM: Vague and
10 ambiguous.
11 If you understand what she
12 means.
13 THE WITNESS: Yeah, I'm of
14 the opinion that his protocol
15 should be applied to no
16 population.
17 BY MS. GEMAN:
18 Q. Do you see any clinical
19 difference between -- or strike that.
20 Let me ask it more
21 generally, if I could.
22 Do you see any difference
23 between the general population and the
24 class here in terms of cancer risk?

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1 A. I think I'm going to answer
2 it in the other direction. So the only
3 exposure we adjust any national cancer
4 screening guidelines for is cigarette
5 smoking. And you have to have a certain
6 number of pack-years in a certain age
7 range.
8 We don't adjust screening
9 protocols for any exposure with the
10 exception of number of pack-years in a
11 certain age range.
12 Q. So the people ultimately
13 seeing this deposition will be entitled
14 to an answer to this question.
15 Do you see any difference
16 between the general population and the
17 class here in terms of cancer risk?
18 MR. KUM: Objection. Vague
19 and ambiguous. Asked and
20 answered.
21 Go ahead, Doctor.
22 THE WITNESS: I don't know
23 that they are any different from
24 the general population.

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1 I don't know -- I don't know
2 that they -- I don't see why
3 they're any different from the
4 general population, I would say,
5 based on any potential impurity.
6 We don't -- I'll give you a good
7 example.
8 Asbestos is a very well
9 defined carcinogen with a very
10 well defined literature.
11 We do not change the
12 screening recommendations for
13 patients with documented asbestos
14 exposure.
15 The only exposure for which
16 there is a specified screening
17 indication is tobacco, certain
18 number of pack-years, certain age
19 range.
20 BY MS. GEMAN:
21 Q. How long after it was clear
22 in the literature that tobacco was a
23 carcinogen was it that the tobacco
24 protocol became embedded in the cancer

<p style="text-align: right;">Page 66</p> <p>1 screening guidelines?</p> <p>2 MR. KUM: Objection. Vague</p> <p>3 and ambiguous.</p> <p>4 THE WITNESS: That's</p> <p>5 actually a great question because</p> <p>6 it speaks to the point that it</p> <p>7 takes years and decades, even when</p> <p>8 you have an established</p> <p>9 carcinogen, to prove that</p> <p>10 screening -- established human</p> <p>11 carcinogen to prove that screening</p> <p>12 confers any benefit.</p> <p>13 We've been trying to figure</p> <p>14 out for years if screening for</p> <p>15 lung cancer conferred any benefit.</p> <p>16 So it was a big deal ten years ago</p> <p>17 with the results of the national</p> <p>18 cancer lung trial using low dose</p> <p>19 spiral CT that there was actually</p> <p>20 a benefit to that class of</p> <p>21 patients.</p> <p>22 And just to be clear, it</p> <p>23 takes -- you have to screen 320</p> <p>24 patients to find one with cancer.</p>	<p style="text-align: right;">Page 68</p> <p>1 stop now. But whenever you get to</p> <p>2 a natural breaking point, can we</p> <p>3 take a comfort break?</p> <p>4 MS. GEMAN: Sure.</p> <p>5 THE WITNESS: I would</p> <p>6 actually love a comfort break.</p> <p>7 BY MS. GEMAN:</p> <p>8 Q. I'll just ask a couple more</p> <p>9 questions, and we'll do that. Otherwise,</p> <p>10 the thought will go right out of my head.</p> <p>11 You acknowledge that</p> <p>12 screening with the use of low dose CT</p> <p>13 reduces mortality from lung cancer,</p> <p>14 correct?</p> <p>15 A. There is an indication. The</p> <p>16 expert opinion put forward by the United</p> <p>17 States Preventive Task Force, that for</p> <p>18 patients that have smoked 20 years and</p> <p>19 are between the ages -- I believe, it's</p> <p>20 55 and 80, that there is a potential</p> <p>21 benefit to screening without undue risk.</p> <p>22 So it's a very specific</p> <p>23 range, duration of exposure, and a very</p> <p>24 specific age range.</p>
<p style="text-align: right;">Page 67</p> <p>1 And what's important here is</p> <p>2 we can screen for a lot of things,</p> <p>3 but we have to show that it</p> <p>4 confers benefit, and equally</p> <p>5 importantly we have to assess the</p> <p>6 magnitude of harm.</p> <p>7 So again, you know, a study</p> <p>8 makes it into New England Journal</p> <p>9 and it's practice-changing. And</p> <p>10 this was the first after years,</p> <p>11 decades, to show benefit to a</p> <p>12 screening protocol.</p> <p>13 And to your point, we have,</p> <p>14 I think, known about the</p> <p>15 carcinogenicity of tobacco smoke</p> <p>16 for years and decades even. I</p> <p>17 don't know when the original</p> <p>18 recognition of the risk of tobacco</p> <p>19 was. I would actually love to</p> <p>20 know that.</p> <p>21 MR. KUM: Counsel, we've</p> <p>22 been going about an hour.</p> <p>23 Whenever you get to a natural --</p> <p>24 I'm not saying that you should</p>	<p style="text-align: right;">Page 69</p> <p>1 Q. The New England Journal of</p> <p>2 Medicine study to which you referred did</p> <p>3 not only study for that population before</p> <p>4 reaching its conclusion about the</p> <p>5 efficacy of low dose CT screening,</p> <p>6 correct?</p> <p>7 A. I don't know that specific.</p> <p>8 I've brought up the New England Journal.</p> <p>9 That was the hallmark study. I didn't</p> <p>10 study the other populations. I really</p> <p>11 just related it to the updated screening</p> <p>12 recommendation that became the standard</p> <p>13 of good practice.</p> <p>14 Q. But I just want the record</p> <p>15 to be very clear.</p> <p>16 Do you agree, full stop,</p> <p>17 with this conclusion that screening with</p> <p>18 the use of low dose CT reduces mortality</p> <p>19 from lung cancer?</p> <p>20 A. I think that is an</p> <p>21 incomplete statement, without putting in</p> <p>22 the duration of exposure and the specific</p> <p>23 ages where it becomes reasonable to test</p> <p>24 for it.</p>

<p>Page 70</p> <p>1 It is a very strict 2 definition there. 3 Q. So if the national lung 4 screening trial research team concluded 5 that screening with the use of low dose 6 CT he reduces mortality from lung cancer, 7 would you disagree with that conclusion? 8 MR. KUM: Objection. 9 Assumes facts not in evidence. 10 You can go ahead and answer. 11 THE WITNESS: I don't really 12 know what that question means from 13 a medical lens. It was the first 14 study to show benefit to screening 15 within a defined population with 16 an acceptable risk/benefit 17 profile. 18 BY MS. GEMAN: 19 Q. And again, you're not 20 claiming that the conclusion reached by 21 the national lung screening trial 22 research team was limited to those 23 specific smoker profiles, correct? 24 A. I don't remember the exact</p>	<p>Page 72</p> <p>1 A. So we are taught to look at 2 evidence based medicine. We do certainly 3 analyze the research as it comes out. 4 I appreciate that the United 5 States Preventive Task Force agreed, and 6 I say so because they have an 7 extraordinary panel, as I mentioned 8 before, of experts who design screening 9 protocols. 10 What I actually find 11 interesting is that, again, I mention 12 there's a literature watch that they 13 follow, and the new debate with the 14 screening guidelines is whether or not it 15 serves black Americans appropriately 16 since they may present differently and 17 they're currently analyzing the 18 literature. 19 So I appreciate that they 20 keep their mind out and keep mind open 21 and they keep updated with the latest 22 studies and findings. 23 Q. Do you agree that the 24 special screening protocols for heavy</p>
<p>Page 71</p> <p>1 details. What I think is important is 2 the United States Preventive Task Force, 3 You know, they have, like, a literature 4 watch. And if an important paper comes 5 up, they convene and address it. 6 And that group of experts 7 decided it was important enough and 8 limited the testing looking at the 9 benefit and magnitude of harm to favor 10 the testing for patients between 55 and 11 80 who had smoked 20 pack-years. 12 MS. GEMAN: Okay. We can 13 take a break. 14 THE WITNESS: Thank you. 15 THE VIDEOGRAPHER: 10:18. 16 We are off the video record. 17 (Short break.) 18 THE VIDEOGRAPHER: 10:38. 19 We are on the video record. 20 BY MS. GEMAN: 21 Q. Do you agree that the 22 special screening protocols for heavy 23 tobacco smokers in the guidelines are 24 appropriate?</p>	<p>Page 73</p> <p>1 tobacco smokers in the guidelines are 2 appropriate? 3 A. Yes. 4 Q. Why? 5 A. Well, it took decades to 6 find a randomized control trial that 7 could identify something that might help. 8 Again, an earlier diagnosis, I believe, 9 again, the number needed to screen is 1 10 in 320. And they looked at it with a 11 balance with the risk of biopsy, and 12 there's obviously established risks when 13 you biopsy a lung tumor in the thorax. 14 And so I feel comfortable 15 using those screening tools. In fact in 16 our practice we have electronic medical 17 records. They are particularly designed 18 for primary care. But I see them on the 19 side of the screen. 20 And the goal there, to 21 maintain the standard of care, is to 22 offer the patient that study. That's not 23 me. That's the primary care. But I 24 appreciate that it has become the</p>

<p style="text-align: right;">Page 74</p> <p>1 national standard of care to offer the 2 patients that study. 3 Q. And when you say identify 4 something that might help, what do you 5 mean? 6 A. So you always want to find a 7 cancer earlier when you can. It turns 8 out to be a very complicated science. 9 And, you know, people think 10 there is a test, you should just take it. 11 And they don't always understand that it 12 may help them live longer or better and 13 that there are risks associated. 14 And to be very clear, I hate 15 cancer, right, like if I could, find 16 every cancer early and treat curatively, 17 curative intent. 18 Yesterday I told one new 19 patient that they would have two and a 20 half years to live with chemotherapy, 21 life with chemotherapy. I told one 22 patient that it was six months with or 23 without treatment, and I told one patient 24 it was weeks.</p>	<p style="text-align: right;">Page 76</p> <p>1 extra screening? 2 MR. KUM: Objection. Calls 3 for speculation. Incomplete 4 hypothetical. 5 THE WITNESS: I can answer? 6 MR. KUM: You can answer. 7 Doctor, just as a reminder 8 I'm just objecting for the record. 9 Unless I specifically instruct you 10 not to answer, you need to answer 11 her question. 12 THE WITNESS: I think until 13 it was established, again since 14 you're doing biopsies or surgeries 15 within the thorax, that the 16 benefit outweighed the risk. 17 I don't know that it would 18 be worth the radiation exposure. 19 I don't know that that technology 20 for low dose spiral CT was 21 available then. 22 So I can't really speak to 23 that. 24 But again, you don't want to</p>
<p style="text-align: right;">Page 75</p> <p>1 So you have to understand 2 how passionately I wish that there were 3 tests that could find this. And I 4 appreciate that that's Dr. Kaplan's wish 5 also. We are on the front lines caring 6 for the most vulnerable patients. 7 And so, if there is a 8 validated intervention that meets the 9 level of approval based on the research 10 by the United States Preventative Task 11 Force, I'm appreciative of that national 12 standard of care. 13 Q. If the -- so the tobacco 14 screening protocol came into existence on 15 date X. We don't know when it was, but 16 it was a certain date, correct? 17 A. You mean through the United 18 States Preventative Task Force. 19 Q. Yes. 20 A. I think it was 2011. 21 Q. 2000 -- 22 A. '11. 23 Q. '11. Would it have been 24 helpful to patients in 2008 to get that</p>	<p style="text-align: right;">Page 77</p> <p>1 do a test that's risky unless you 2 have some data showing that the 3 magnitude of benefit is greater 4 than the magnitude of harm, and it 5 met that threshold. 6 BY MS. GEMAN: 7 Q. So you would not have 8 supported a patient undergoing that 9 screening protocol in 2010? 10 A. I think it was only offered 11 on clinical trial, which is how these are 12 usually delivered. 13 Q. Okay. But you offer your 14 patients clinical trials all the time, 15 correct? 16 A. I always try and put 17 patients on a clinical trial when I have 18 the opportunity. 19 Q. So then would you have 20 supported a patient undergoing that 21 screening protocol in 2010? 22 A. Only within the context of a 23 clinical trial. 24 Q. Okay. But the answer then</p>

<p style="text-align: right;">Page 78</p> <p>1 is yes, you would have supported a 2 patient undergoing that screening 3 protocol in 2010? 4 MR. KUM: Objection. 5 Misstates testimony. 6 You can answer again. 7 THE WITNESS: If it were 8 within the context of a clinical 9 trial, I would support it. 10 BY MS. GEMAN: 11 Q. Are there other 12 circumstances under which you would 13 support a screening protocol that is not 14 yet embedded in the task force? 15 A. Can you give me an example, 16 please? 17 Q. Well, you said a clinical 18 trial is one; is that right? 19 A. If there were clinical trial 20 specific to that question. Again, this 21 is much more in the primary care domain. 22 They already have been diagnosed with 23 cancer by the time they reach me. So 24 it's a little hard for me to speak to</p>	<p style="text-align: right;">Page 80</p> <p>1 inform their care? How does it help 2 them? 3 If you put them on telemetry 4 which monitors their heart rate, they're 5 tethered. They may get confused. They 6 may fall. 7 You can't give them a 8 medicine to slow down the heart rate, 9 because the cause of the elevated heart 10 rate is the fever. Are you going to get 11 a cardiology consult? There's -- my 12 point is, you have to know what to do 13 with every test you order. 14 Q. I appreciate that. So I'm 15 going to ask you the same question again. 16 And just, please, if you could answer the 17 question that's asked. 18 Are there other 19 circumstances under which you would 20 recommend a screening protocol that is 21 not yet embedded in the task force? 22 A. The -- I would say, you 23 know, again through my cancer lens, 24 because I'm not on the front lines of</p>
<p style="text-align: right;">Page 79</p> <p>1 that exact circumstance. 2 But I worry that if I order 3 a test, I don't know what to do with it. 4 And I could harm the patient in the 5 workup of -- I'll put it to you this way. 6 We can order a lot of tests. 7 And there's a lot of really fun tests to 8 order that sound amazing. But every time 9 you order a test -- I teach this to the 10 residents and med students and fellows 11 all the time -- you have to know what 12 you're going to do with the result. 13 And, you know, I'll give you 14 a noncancer example, and I'll give you a 15 cancer example. 16 So if you have a patient 17 with a fever in a hospital, they may be 18 tachycardic. And a resident or a student 19 will see that elevated heart rate and 20 order an EKG. 21 And I ask them, you know, 22 why did you order the EKG? They are 23 tachycardic. What are you going to do 24 with that information? How does it</p>	<p style="text-align: right;">Page 81</p> <p>1 primary care right now. 2 If I had a patient with a 3 hereditary cancer syndrome, not only -- 4 and, you know, I can say specifically -- 5 we have a dedicated GI genetics program, 6 so I refer to them. They then manage the 7 timing of the screening. 8 I do think some of this is 9 within the caveats to the recommended 10 protocol for high risk population. But 11 that would be an example of a population 12 that's sort of ordering a test or 13 consultation based on a high risk 14 feature, cancer feature for that 15 individual patient. 16 Obviously, it's individual 17 care and personalizing the care to the 18 patient. 19 Q. So other than clinical 20 trials and hereditary cancer syndrome, 21 are there other circumstances under which 22 you would recommend screening protocols 23 that are not embedded in the task force? 24 A. And actually I think these</p>

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<p>1 are in the task force. So inflammatory 2 bowel disease, you would refer. And 3 again, I'm not ordering a screening. I'm 4 referring to an expert who knows how to 5 manage that screening. So it's fraught. 6 It's fraught.</p> <p>7 And you didn't want an 8 example, but may I offer one?</p> <p>9 Q. Well, I'd like to, if I 10 could, follow up on what you just said.</p> <p>11 How is -- how is the 12 inflammatory bowel disease screening that 13 you recommend in the task force? Do you 14 mean it's in the caveats, or -- I just 15 want to understand.</p> <p>16 A. I think it's in the task 17 force recommendations that there are 18 different intervals within -- as we were 19 speaking, colorectal screening for a 20 certain population.</p> <p>21 Q. And what are the caveats?</p> <p>22 A. So the intervals of -- and 23 actually, I think this only applies to 24 colon cancer screening. There's no</p>	<p>1 usually -- I remember that being a higher 2 risk.</p> <p>3 I don't know that there's 4 any other caveat. There might be for 5 prostate cancer with no BRCA. But I 6 don't know for sure. I would have to 7 look at it.</p> <p>8 Q. Do you support special 9 screening for people who may be BRCA 10 positive?</p> <p>11 A. It depends. So for example, 12 with pancreas cancer, BRCA1 doesn't 13 really infer greater risk, but BRCA2 14 does. So again, it's individualized to 15 the patient.</p> <p>16 Q. Well, within that same 17 patient, that wouldn't be two separate 18 BRCA tests, correct? Wouldn't it just be 19 a test for BRCA and the information might 20 be inform relevant to one cancer than 21 another, but it's the same test; is that 22 correct?</p> <p>23 A. There is -- you know, 24 there's different -- there's Myriad,</p>
Page 83	Page 85
<p>1 special indication for esophagogastric or 2 pancreas or others deemed as high risk. 3 I believe the interval was changed of the 4 endoscopy screening.</p> <p>5 Q. So I'm -- this might be my 6 misunderstanding. You referred earlier 7 to the caveats protocol. Can you tell me 8 what that is?</p> <p>9 A. I'm not sure what that means 10 in terms of caveat protocol. I know 11 within the United States preventive task 12 force, there's a recognition that 13 hereditary cancer syndrome and 14 inflammatory bowel disease confers a 15 higher risk of bowel cancer, and the 16 interval of screening is shortened from 17 ten to five years.</p> <p>18 Q. Are there any other 19 recognitions of high risk categories in 20 the USPSTF?</p> <p>21 A. So they only recommend 22 screening for a handful of cancers. I 23 think, again, the hereditary cancer 24 syndrome changes mammography. That's</p>	<p>1 there's Ambry, there are panels that look 2 for the most concerning. They test a lot 3 of genes. It's usually about 10 to 12.</p> <p>4 We actually have specialized 5 gene profiles for every -- for every 6 disease site.</p> <p>7 Q. No, but my question was a 8 little different, which is when you -- 9 when you take that test, it's not like 10 there's a test for BRCA that -- the 11 pancreas BRCA versus the breast BRCA. 12 You're just testing for BRCA.</p> <p>13 A. Oh, I'm sorry. It's one, 14 you know, deleterious gene in the panel.</p> <p>15 Q. It's one allele?</p> <p>16 A. Yes.</p> <p>17 Q. And likewise for those 10 to 18 12 that you mentioned, each one, it's not 19 like there's organ specific alleles. You 20 have the allele or you don't; is that 21 right?</p> <p>22 A. Correct.</p> <p>23 Q. And so do you support 24 special screening for people who may be</p>

<p style="text-align: right;">Page 86</p> <p>1 BRCA positive?</p> <p>2 A. So again, I refer them to --</p> <p>3 we have cancer risk evaluation program,</p> <p>4 as do most academic institutions. I'm</p> <p>5 sure Dr. Kaplan has access to that at</p> <p>6 Rush as well. And we usually refer them</p> <p>7 to them, and then they direct the</p> <p>8 screening.</p> <p>9 We also, you know -- we test</p> <p>10 a patient for, you know, any hereditary</p> <p>11 cancer syndromes. And if we identify it,</p> <p>12 we refer them, and then they manage the</p> <p>13 patient and any evaluation for their</p> <p>14 kindred, for their family.</p> <p>15 Q. So you do support special</p> <p>16 screening for people who may be BRCA</p> <p>17 positive?</p> <p>18 A. I think that's, you know, as</p> <p>19 stated within the guidelines,</p> <p>20 appropriate. You don't want to miss that</p> <p>21 family or that patient.</p> <p>22 Q. What do you mean by miss</p> <p>23 that family or the patient?</p> <p>24 A. Well, if you don't test, you</p>	<p style="text-align: right;">Page 88</p> <p>1 Q. And would you support -- and</p> <p>2 I'm sorry.</p> <p>3 Was the company culpable in</p> <p>4 not having sufficient workplace</p> <p>5 protections?</p> <p>6 MR. KUM: Objection. Calls</p> <p>7 for a legal conclusion.</p> <p>8 THE WITNESS: I just</p> <p>9 testified about his case.</p> <p>10 BY MS. GEMAN:</p> <p>11 Q. Got it.</p> <p>12 A. And I don't really -- I</p> <p>13 didn't even know what happened until I</p> <p>14 later asked to get a copy of the</p> <p>15 deposition to present to you.</p> <p>16 Q. And I think you mentioned</p> <p>17 that there was a lot of cancers in the</p> <p>18 part of the body that -- where there had</p> <p>19 been a hood.</p> <p>20 MR. KUM: You have to give a</p> <p>21 verbal response.</p> <p>22 Sorry.</p> <p>23 THE WITNESS: Yes. Sorry.</p> <p>24 BY MS. GEMAN:</p>
<p style="text-align: right;">Page 87</p> <p>1 don't know. And if you identify the</p> <p>2 patient, you refer them.</p> <p>3 Q. Have you ever had occasion</p> <p>4 to study screening protocols that arose</p> <p>5 out of lawsuits or mass accidents?</p> <p>6 A. No.</p> <p>7 Q. Have you ever studied</p> <p>8 screening protocols for mutagens without</p> <p>9 a threshold?</p> <p>10 MR. KUM: Objection. Vague.</p> <p>11 And ambiguous.</p> <p>12 MS. GEMAN: Sure.</p> <p>13 BY MS. GEMAN:</p> <p>14 Q. Have you ever -- have you</p> <p>15 ever studied screening protocols based on</p> <p>16 a person's exposure to a mutagenic agent?</p> <p>17 A. No. The patient that I</p> <p>18 testified for, that wasn't a screening</p> <p>19 protocol issue.</p> <p>20 Q. Okay. And with that</p> <p>21 patient, was it limited to -- were the</p> <p>22 concerns about the workplace conditions</p> <p>23 limited to his workplace facility?</p> <p>24 A. Yes.</p>	<p style="text-align: right;">Page 89</p> <p>1 Q. Would you have -- were any</p> <p>2 of the -- were any of the types of</p> <p>3 cancers that that gentleman had cancers</p> <p>4 where early testing could affect the</p> <p>5 course of the illness?</p> <p>6 A. No.</p> <p>7 Q. Because they were</p> <p>8 untreatable cancers?</p> <p>9 A. There are no United States</p> <p>10 Preventive Task Force guidelines for</p> <p>11 skin. Actually, it's not -- I should say</p> <p>12 it's not recommended for skin. There are</p> <p>13 no screening recommendations for pancreas</p> <p>14 cancer. There is no screening</p> <p>15 recommendation -- well, I should say it's</p> <p>16 I, they rate it as an I, which is their</p> <p>17 lowest level of evidence.</p> <p>18 So I think pancreas is an I.</p> <p>19 Skin is an I. Melanoma -- so that's</p> <p>20 melanoma and basal cell and testicular,</p> <p>21 there are no recommendations to screen</p> <p>22 for those cancers.</p> <p>23 Q. If skin cancer is caught</p> <p>24 early, that can help stop its spread,</p>

<p style="text-align: right;">Page 90</p> <p>1 correct?</p> <p>2 A. Certainly want to have eyes</p> <p>3 on the skin. But I don't know how -- and</p> <p>4 I don't know how or why it is not in the</p> <p>5 protocol.</p> <p>6 Q. But my question is separate</p> <p>7 from what's in the protocol. If skin</p> <p>8 cancer is caught early, that can help</p> <p>9 stop its spread, correct?</p> <p>10 A. Which skin cancer?</p> <p>11 Q. Any skin cancers.</p> <p>12 MR. KUM: Vague and</p> <p>13 ambiguous.</p> <p>14 If you know.</p> <p>15 THE WITNESS: So basal cells</p> <p>16 tend to stay localized.</p> <p>17 So -- and then squamous</p> <p>18 cells can spread. Melanoma can</p> <p>19 spread.</p> <p>20 BY MS. GEMAN:</p> <p>21 Q. Okay. So if the cancer is</p> <p>22 caught early, can it help stop the spread</p> <p>23 of melanoma or squamous cell skin cancer?</p> <p>24 A. So I'm not sure why the</p>	<p style="text-align: right;">Page 92</p> <p>1 CAPS5. And it started in 2014. And it</p> <p>2 ends -- hopefully it will be accrued by</p> <p>3 2025. And their goal -- because this is</p> <p>4 an unanswered question. And it's been</p> <p>5 very elusive. And their goal is to see</p> <p>6 if you do -- I can't remember if it's</p> <p>7 every six months or yearly, endoscopic</p> <p>8 ultrasounds, and you test -- you give</p> <p>9 them secretin and you test the pancreas</p> <p>10 juice or you biopsy a cyst.</p> <p>11 And they are seeing if</p> <p>12 scheduled interval of testing affects the</p> <p>13 outcome.</p> <p>14 I -- there is another study</p> <p>15 that is very disheartening. And they</p> <p>16 took about -- let's see, it was almost</p> <p>17 700 patients, and they did endoscopic</p> <p>18 ultrasounds, and I can't remember if it's</p> <p>19 MRI or CT at very regular intervals.</p> <p>20 And they tracked -- these</p> <p>21 were patients, like, BRCA, hereditary</p> <p>22 cancer syndromes that are known to have</p> <p>23 an increased risk, about 5 to 7 percent</p> <p>24 risk.</p>
<p style="text-align: right;">Page 91</p> <p>1 decision was made that the evidence isn't</p> <p>2 robust enough to make that a</p> <p>3 recommendation. I can't speak to why to</p> <p>4 that level of evidence.</p> <p>5 Q. I appreciate that. My</p> <p>6 question is a little different, which is,</p> <p>7 in your opinion as an oncologist, if</p> <p>8 melanoma or squamous skin cancer is</p> <p>9 caught early, can that help prevent its</p> <p>10 spread?</p> <p>11 A. I think probably yes. I</p> <p>12 would assume yes. But I don't know about</p> <p>13 the screening protocol, if that actually</p> <p>14 helps it be caught early. I guess that</p> <p>15 might be the issue. We always -- that's</p> <p>16 what I would say.</p> <p>17 Q. And can certain pancreatic</p> <p>18 cancers be prevented from metastasizing</p> <p>19 if caught early enough?</p> <p>20 A. So this is a hard, hard one.</p> <p>21 And believe me, everyone is trying to</p> <p>22 figure it out.</p> <p>23 So there -- in the --</p> <p>24 there's an ongoing clinical trial called</p>	<p style="text-align: right;">Page 93</p> <p>1 And they tracked them. It</p> <p>2 actually took 16 years to get any kind of</p> <p>3 an answer. And of the 20 percent -- so</p> <p>4 that's about 70 patients who had a cyst</p> <p>5 or something growing, I think 10 or 12 of</p> <p>6 them had a frank cancer develop, and less</p> <p>7 than ten were able to go to the OR with</p> <p>8 curative intent. And I think that their</p> <p>9 five-year survival -- it wasn't</p> <p>10 100 percent, but it was a little higher.</p> <p>11 But again, this is 16 years</p> <p>12 of invasive procedures. And the problem</p> <p>13 is, we actually still don't have an</p> <p>14 answer for that population.</p> <p>15 There are three lesions</p> <p>16 that, you know, just like with colon</p> <p>17 cancer, you take it from polyp to cancer</p> <p>18 over, you know, years, decades, which is</p> <p>19 why they set the threshold of the</p> <p>20 intervals.</p> <p>21 So there's three lesions</p> <p>22 that they follow. And one is IPMN, which</p> <p>23 is an intraductal mucinous, IP --</p> <p>24 mucinous neoplasm. And the next one is</p>

<p>Page 94</p> <p>1 MCN, the mucinous cystic neoplasm. And</p> <p>2 both of those have the potential to turn</p> <p>3 into cancer, but it's very low.</p> <p>4 The most likely is something</p> <p>5 called PanIN. And unfortunately these</p> <p>6 lesions are usually under 5 millimeters.</p> <p>7 You can't see them on a scan. You really</p> <p>8 can only see them under a microscope.</p> <p>9 And they transform from PanIN 1 to PanIN</p> <p>10 3. There's -- over years, they can</p> <p>11 follow these things.</p> <p>12 And the problem with them is</p> <p>13 they may not be really visible to the</p> <p>14 human eye. This is -- this is the</p> <p>15 problem with this cancer.</p> <p>16 And so they -- but they go</p> <p>17 right to the vein. And the way the blood</p> <p>18 flows, the cancer goes into the vein and</p> <p>19 goes right to the liver.</p> <p>20 And so, you know, part of</p> <p>21 that has been the issue. We cannot</p> <p>22 reliably, even in a high risk population,</p> <p>23 know that screening is helping in any</p> <p>24 meaningful way. We're still waiting for</p>	<p>Page 96</p> <p>1 really rare cancer. It's designated as</p> <p>2 an orphan cancer. It's only 3 percent of</p> <p>3 all cancers. I think the number is 13 in</p> <p>4 100,000 people will develop pancreas</p> <p>5 cancer. Of course it has a really bad</p> <p>6 reputation, because it's difficult to</p> <p>7 treat.</p> <p>8 And just for context,</p> <p>9 cancers that have established screening</p> <p>10 protocols that are effective, breast</p> <p>11 cancer, the risk of a woman developing</p> <p>12 breast cancer, I think is 1 in 8 in her</p> <p>13 lifetime. And the general risk for colon</p> <p>14 cancer is 1 in 25.</p> <p>15 So that's just to put in</p> <p>16 perspective 13 in 100,000 people will</p> <p>17 develop pancreas cancer.</p> <p>18 And that's why it has an</p> <p>19 orphan designation. In the U.S. I think</p> <p>20 it's about 56,000 cases per year.</p> <p>21 Q. So in the Johnson & Johnson</p> <p>22 case that you -- for which you provided</p> <p>23 testimony, would you have supported</p> <p>24 workers who were similarly situated to</p>
<p>Page 95</p> <p>1 that data.</p> <p>2 And, you know, there is</p> <p>3 potential harm. They stopped screening,</p> <p>4 to be very clear, if -- they kind of base</p> <p>5 it on the patient's life expectancy. And</p> <p>6 interestingly, these cancers develop at</p> <p>7 the same age as regular patients that</p> <p>8 develop pancreas cancer, so 65, 70.</p> <p>9 Again, they followed them</p> <p>10 16 years.</p> <p>11 So, it's -- and there's no</p> <p>12 blood test that's been reliable.</p> <p>13 So it's -- it's a difficult</p> <p>14 issue. And that's why there's, you know,</p> <p>15 no guidelines. We're really trying to do</p> <p>16 clinical trials to answer the question.</p> <p>17 And there's not tremendous</p> <p>18 optimism, even for these higher risk</p> <p>19 patients, that we're going to be able to</p> <p>20 figure it out.</p> <p>21 And just one more thing. So</p> <p>22 pancreas -- you hit my sweet spot. I</p> <p>23 trained in pancreas.</p> <p>24 Pancreas is actually a</p>	<p>Page 97</p> <p>1 your patient being given notification and</p> <p>2 the option to screen for skin cancers?</p> <p>3 MR. KUM: Objection.</p> <p>4 Incomplete hypothetical. Assumes</p> <p>5 facts not in evidence.</p> <p>6 THE WITNESS: I don't know</p> <p>7 that it was known. I can't really</p> <p>8 speak to that time.</p> <p>9 There's -- even for patients</p> <p>10 with heavy history of burns,</p> <p>11 sunburns in childhood, there</p> <p>12 aren't any clear guidelines.</p> <p>13 I will say, certainly,</p> <p>14 again, falls between the patient</p> <p>15 and their caregiver and the clinic</p> <p>16 physician or provider, that if,</p> <p>17 you know, the patient reported</p> <p>18 that, they'd probably pay more</p> <p>19 attention to the skin, just like</p> <p>20 if a patient reported a symptom,</p> <p>21 they would pay attention to the</p> <p>22 symptom.</p> <p>23 BY MS. GEMAN:</p> <p>24 Q. So you would support the</p>

<p>Page 98</p> <p>1 patients being notified of the need to 2 pay more attention to their skin? 3 A. I don't know. I can't speak 4 to that time. I don't know that he knew 5 it at the time or that it was known. I 6 actually have no way to know that answer. 7 Q. So you can't answer that 8 question, as to whether you would support 9 anyone -- you know, others who may have 10 worked under the same conditions as your 11 patient being notified that they should 12 pay particular attention to their skin as 13 a result of an exposure in the workplace? 14 MR. KUM: Asked and 15 answered. 16 THE WITNESS: I don't know 17 what was known or not known. And, 18 you know, some people get exposed 19 to a lot of radiation and never 20 get cancer. And some don't. I 21 think at that time, since it was 22 all unknown, he was getting, you 23 know, more evaluations because of 24 his history of growing up at the</p> <p>Page 99</p> <p>1 shore. 2 But I don't think it was 3 known. And so I really can't 4 speak to that. 5 BY MS. GEMAN: 6 Q. But sitting here now, if 7 there were other similar workers to your 8 patient, meaning people who worked under 9 the same workplace conditions, don't you 10 think they should have been advised about 11 the risk exposure? 12 A. Well -- 13 MR. KUM: Objection. Calls 14 for speculation. Assumes facts 15 not in evidence. 16 BY MS. GEMAN: 17 Q. You can answer. 18 A. I'll just say that he didn't 19 die from metastatic melanoma or basal 20 cell cancer. They were surgically 21 removed when they were seen. He died of 22 a cancer that's deep inside the body that 23 you can't screen for. 24 So, you know, I don't know</p>	<p>Page 100</p> <p>1 how to answer that question. 2 Q. Well, I wasn't asking how 3 that -- under those terrible facts how 4 that gentleman died. 5 What I was asking is whether 6 you would support notification to other 7 workers, working under the same 8 conditions, that they should pay special 9 attention to, at minimum, their skin? 10 MR. KUM: Calls for 11 speculation. 12 THE WITNESS: I don't know. 13 I don't know the answer. It's way 14 back in time in a circumstance 15 that I really can't speak to. 16 BY MS. GEMAN: 17 Q. What is C8? 18 A. Excuse me. 19 Q. What is carbon 8? 20 A. A molecule. An element. I 21 don't know what you're -- 22 Q. Fair enough. Have you ever 23 heard of something called PFOA? 24 A. Not that I recall.</p> <p>Page 101</p> <p>1 Q. I'm going to butcher this, 2 so bear with me. Have you ever heard of 3 ammonium perfluorooctanoate? 4 A. No. I've heard of a lot of 5 things in all of my training. I can't 6 remember that exact. 7 Q. Okay. Because I butchered 8 it so badly, I'm going to ask the court 9 reporter's indulgence in spelling it. So 10 it's ammonium, A-M-M-O-N-I-U-M, 11 P-E-R-F-L-U-O-R-O-O-C-T-A-N-O-A-T-E. 12 So just to circle back, 13 whether known as carbon 8 or PFOA or 14 ammonium perfluorooctanoate, et cetera, 15 have you ever heard of that molecule in 16 connection with cancer? 17 A. It's not familiar. I 18 don't -- you know, have I ever heard of 19 it? I took organic chemistry. I may 20 have. 21 Q. Okay? 22 A. But there's a lot back in, 23 you know, 25 or 30 years ago that I -- 24 just trying to be very truthful. I</p>
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1 certainly don't remember it sitting here.
2 Q. Okay. Do you remember
3 generally that a lot of -- that there are
4 a number of carbon molecules used in --
5 not just C8, but used in industrial
6 settings that can be carcinogenic?
7 MR. KUM: Objection.
8 Outside the scope of her report.
9 THE WITNESS: Yeah, I think,
10 again, I was not -- I'm not a
11 causative witness. So I would
12 rather direct the discussion, if I
13 may, to the content of my letter,
14 which speaks to Dr. Kaplan's
15 proposed medical monitoring.
16 BY MS. GEMAN:
17 Q. Fair enough. But I am
18 entitled to the answer. Do you have
19 knowledge as to whether there are certain
20 carbon molecules regularly used in
21 industrial settings that can, under some
22 circumstances, be carcinogenic?
23 MR. KUM: Same objections.
24 If you know.

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1 THE WITNESS: I don't know
2 specific molecules. I know there
3 are industries of concerns like
4 metal and rubber. I know there
5 are inhaled concerns from certain
6 agents. But I don't really have a
7 list of them.
8 BY MS. GEMAN:
9 Q. Does the USPTF have special
10 screening guidelines for people exposed
11 to excessive C8, carbon 8?
12 A. I don't think so.
13 Q. If there were a medical
14 monitoring program approved by a court
15 that provided that individuals improperly
16 exposed to excessive levels of C8 --
17 under which those individuals could
18 receive medical monitoring, would you
19 think that was inappropriate?
20 MR. KUM: Objection.
21 Outside the scope of her report.
22 Calls for speculation.
23 If you have an opinion,
24 Doctor.

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1 THE WITNESS: It's really
2 outside of the scope of the
3 report.
4 I focused on the potential
5 exposure of an impurity. And I
6 will contend again that within the
7 construct of the national
8 guidelines, the only modification
9 for an exposure is 20 years of
10 tobacco from age 55 to 80 with the
11 example then, again, that
12 asbestos, which is known to
13 increase risk; radon, which is
14 known to increase risk, is not
15 part of that recommendation.
16 And, you know, another point
17 of knowledge is, for example, we
18 know that Barrett's esophagus,
19 which is a known precancerous
20 condition with a rate of
21 conversion to frank malignancy of
22 1 to 3 percent every year, also
23 does not change the guidelines.
24 So we have known human

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1 carcinogen exposure that don't
2 change the national guidelines,
3 and known premalignant conditions
4 that don't change the guidelines.
5 I can't speak to an exposure
6 about a chemical that I just don't
7 understand to a population that I
8 don't know about.
9 So -- but I -- I can speak
10 to the guidelines and the general
11 premise that exposures don't
12 change cancer screening.
13 BY MS. GEMAN:
14 Q. Okay. But can we agree or
15 do you agree that the presence or not of
16 a screening protocol in the task force,
17 does not prevent an otherwise valid
18 monitoring program from being enacted?
19 MR. KUM: Objection. Calls
20 for speculation. Vague and
21 ambiguous.
22 THE WITNESS: I really don't
23 know.
24 BY MS. GEMAN:

<p style="text-align: right;">Page 106</p> <p>1 Q. Okay. I mean, your upshot 2 is if the monitoring program is not in 3 the guidelines, it shouldn't be done, 4 correct, other than those circumstances 5 which you've already detailed? 6 A. My upshot is that I 7 appreciate the expertise and time that 8 the experts in general internal medicine, 9 pediatrics, biostatistics, health 10 services research, that they put the time 11 in and continue to do so based on the 12 available literature for the average risk 13 population, the asymptomatic population 14 with some added information for the high 15 risk population. 16 Again, noting that there are 17 some high risk populations that -- or 18 someone might say they were high risk, 19 where the benefit of an invasive 20 procedure is not deemed high enough 21 relative to the magnitude of potential 22 harm to change the guideline. 23 Q. Well, you understand that a 24 medical monitoring program ordered by a</p>	<p style="text-align: right;">Page 108</p> <p>1 very specifically addressed the tests put 2 forward by Dr. Kaplan. 3 Q. Okay. So it's not your 4 opinion that any protocol, other than 5 what already exists in the task force is 6 ex-ante inappropriate? 7 MS. GEMAN: Sorry, E-X, 8 A-N-T-E. 9 THE WITNESS: I don't really 10 know what that means. Is it 11 Latin? 12 BY MS. GEMAN: 13 Q. Sure. 14 It's not your opinion that 15 any protocol other than what already 16 exists in the task force, is 17 categorically inappropriate? 18 A. It is my opinion that this 19 protocol put forward by Dr. Kaplan is 20 extremely risky to these patients. And 21 quite honestly, it's not clear to me 22 they're put forward without any evidence 23 relative to the cancers he recommends 24 them for.</p>
<p style="text-align: right;">Page 107</p> <p>1 court after a finding of culpability by 2 defendants does not change the guidelines 3 for people of average risk, correct, but 4 instead focuses on a subpopulation of 5 particularized risk? 6 MR. KUM: Objection. Calls 7 for a legal conclusion. Calls for 8 speculation. 9 THE WITNESS: I don't really 10 know much about that, to be 11 honest. 12 It sounds very specific. 13 BY MS. GEMAN: 14 Q. Well, it's specific and it's 15 general. I mean the question is: Do 16 you -- do you -- is it your view that any 17 screening program is inappropriate, other 18 than the two exceptions that you 19 mentioned, unless it's already set forth 20 in the guidelines? 21 A. I don't feel really 22 comfortable commenting without reviewing 23 it. It sounds like a broad topic. It 24 was not the focus of my report, which</p>	<p style="text-align: right;">Page 109</p> <p>1 I really think I can only 2 speak to what is in my expert letter. 3 And it's really outside of the scope of 4 what I was asked to do and what I 5 prepared for to address this. 6 Q. Well, I am entitled to the 7 answer you're able to give now. Is it 8 your opinion that any protocol, other 9 than what's already extant in the task 10 force, is categorically inappropriate? 11 MR. KUM: Asked and 12 answered. 13 You can answer it again, 14 Doctor. 15 THE WITNESS: I'm just going 16 to say I don't know. 17 BY MS. GEMAN: 18 Q. Okay. 19 A. I don't have enough 20 information. But I can say that this 21 protocol is incredibly risky. And I'm 22 happy to address the different tests and 23 scenarios and risks that could arise from 24 it, for this vulnerable class of cardiac</p>

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1 patients.
 2 Q. Does the -- did the task
 3 force consider and reject the protocol --
 4 strike that.
 5 Does the task force in
 6 addition to its caveats, allow for
 7 change?
 8 A. So again, they have a very
 9 sophisticated literature watch. And if
 10 updated information comes, they very
 11 eagerly consider it.
 12 For example, the last update
 13 for pancreas cancer, they reviewed the
 14 available literature and, again, were
 15 recommended no specific protocol,
 16 screening protocol, either for
 17 asymptomatic average risk patients or
 18 high risk patients based on the evidence.
 19 So I think you're asking me
 20 if they are up-to-date and flexible. And
 21 I would say within the constructs of the
 22 available literature, they are very much
 23 attuned to evidence-based medicine.
 24 Q. So the task force has

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1 caveats, and they are not fixed forever,
 2 they can change?
 3 A. They will update their
 4 recommendations based on any new
 5 important studies or findings. That is
 6 their mandate.
 7 Q. Do you think it is
 8 appropriate for someone who has one or
 9 two biological parents with a marker for
 10 Huntington's to get the test to see if
 11 they have the marker?
 12 A. I don't know much about
 13 this.
 14 I know that if it's offered,
 15 a lot of people don't want to know.
 16 That's actually all I know in that space.
 17 Q. That's all you know in that
 18 space? Okay.
 19 A. Yeah.
 20 Q. What's the -- do you see any
 21 benefit to knowing?
 22 A. Well, it actually speaks a
 23 lot to the screening protocol. You can't
 24 change the outcome, whether you have it

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1 or not. And there's no medical
 2 intervention.
 3 So knowing it earlier won't
 4 change your outcome or overall survival,
 5 which is why I think a lot of patients
 6 elect not to.
 7 So again, that's a very
 8 individual decision, but it plays to the
 9 general point of screening, that you may
 10 identify it earlier but it doesn't change
 11 your prognosis. That's actually -- I
 12 wish I thought of that. That was a good
 13 example.
 14 Q. So to be clear, we agree
 15 that that is a paradigmatic example of
 16 something that you can't change if you
 17 know it?
 18 A. Can you slow down and say
 19 all those words, please?
 20 Q. Sorry. Sure.
 21 To be clear, we agreed that
 22 the marker for Huntington's in the HdG
 23 gene is sort of a paradigmatic example of
 24 something that you can't change. You

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1 can't prevent getting Huntington's. You
 2 can't cure Huntington's if you have it.
 3 Correct?
 4 A. So the paradigm that finding
 5 it earlier doesn't change the outcome.
 6 Yes.
 7 Q. Do you see any benefits,
 8 nonetheless, to somebody being entitled
 9 to find out if they have it?
 10 A. Can you repeat the question?
 11 Q. Sure.
 12 Do you see any benefits to
 13 somebody being entitled to find out if
 14 they have it, it being the HdG marker?
 15 A. So I think it depends on the
 16 person. It's, again, very individual.
 17 Some people would like to know so they
 18 can plan their life and family affairs.
 19 I think a large number would not want to
 20 know because of the anxiety and
 21 psychological distress that it provokes.
 22 So I think there are two
 23 sides to that. That's, I think, as I
 24 recall -- this is years ago, that's some

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1 of the controversy.
2 And again, comes down to,
3 you know, not one-size-fits-all,
4 personalized care in the sacred clinic
5 space between that patient's physician
6 and the individual wishes of the patient.
7 Q. Do you think it's
8 appropriate for someone who has one or
9 two biological parents with Parkinson's
10 to see if they have the LRRK allele?
11 MR. KUM: Objection.
12 Outside the scope.
13 THE WITNESS: Yeah, I don't
14 know about this. I don't know
15 that I can comfortably address
16 this.
17 It's not anything within the
18 mission that I was given to answer
19 to the screening protocol that was
20 put forth by Dr. Kaplan, which is
21 the focus.
22 MR. KUM: Doctor, just to be
23 clear. Ms. Geman is entitled to
24 ask you whatever questions she

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1 wants to ask you.
2 If you happen to have an
3 opinion, then you can answer her
4 question.
5 But if you can't answer it,
6 you can tell her that as well.
7 THE WITNESS: Okay.
8 MR. KUM: I just wanted to
9 let you know.
10 THE WITNESS: I don't know
11 is just sort of the answer.
12 MR. KUM: That's a --
13 THE WITNESS: That's the
14 answer.
15 MR. KUM: -- a perfectly
16 acceptable answer.
17 THE WITNESS: I'm going to
18 go with I don't know.
19 MS. GEMAN: Okay. Fair
20 enough.
21 BY MS. GEMAN:
22 Q. Let's segue back to cancer,
23 to oncology.
24 A. That's my sweet spot.

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1 Q. Do you agree that a Stage 0
2 cancer that has not metastasized is more
3 treatable than cancer that has
4 metastasized?
5 MR. KUM: Objection.
6 Incomplete hypothetical.
7 THE WITNESS: So it's a
8 fascinating question, because we
9 know that not all cancers will
10 progress.
11 And even though we offer
12 surgery or medications, we can't
13 say that this cancer will either
14 grow, progress, within your
15 lifetime.
16 So while it's sort of a
17 comforting thing to say that we
18 offer someone treatment, there's
19 no way to know that it changes
20 their overall survival.
21 And the flip is, if it
22 didn't, they've just been
23 subjected to surgery and
24 potentially other therapies that

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1 are harmful.
2 We always hope to catch it
3 earlier. That would be my dream
4 for every patient.
5 BY MS. GEMAN:
6 Q. And you would treat a Stage
7 0 cancer?
8 A. I don't really know right
9 now what the standard of care is for
10 Stage 0 cancer. There's different cancer
11 types. And that's certainly a field
12 that's had a lot of evolution and nuance
13 since my time in fellowship.
14 Q. Do you agree that cancer
15 screening can prevent certain advanced or
16 incurable cancers?
17 A. I'm going to parse that out
18 a little bit.
19 So cancer screening can --
20 it doesn't -- nothing clearly prevents
21 cancer.
22 Cancer screening is designed
23 to find cancers earlier when they're more
24 amenable to treatment.

<p style="text-align: right;">Page 118</p> <p>1 Q. So again, that's helpful.</p> <p>2 Thank you.</p> <p>3 Do you agree that cancer</p> <p>4 screening followed by appropriate</p> <p>5 treatment can prevent certain advanced or</p> <p>6 incurable cancers?</p> <p>7 A. So the data that seems the</p> <p>8 most promising, or I should say most</p> <p>9 established, is that in terms of cancer</p> <p>10 screening in an asymptomatic population,</p> <p>11 which is validated, is through the task</p> <p>12 force, and includes breast cancer, colon</p> <p>13 cancer, prostate cancer with a negative</p> <p>14 recommendation for screening, and lung</p> <p>15 cancer.</p> <p>16 I don't know what the</p> <p>17 benefit is in other cancers compared to</p> <p>18 the risk.</p> <p>19 Q. And a colonoscopy can both</p> <p>20 screen for and treat a precancer; is that</p> <p>21 correct?</p> <p>22 A. So that's a great question.</p> <p>23 So you do sort of think of</p> <p>24 it as both screening and potentially</p>	<p style="text-align: right;">Page 120</p> <p>1 don't know that data.</p> <p>2 Q. Do you believe that it's the</p> <p>3 same now as it was 35 years ago?</p> <p>4 A. I can't say with any, you</p> <p>5 know, certainty. I really don't know</p> <p>6 that data. I hope so.</p> <p>7 Q. Okay.</p> <p>8 MR. KUM: Whenever you get</p> <p>9 to another stopping point,</p> <p>10 Counsel.</p> <p>11 MS. GEMAN: Sure.</p> <p>12 Should we -- can we go off</p> <p>13 the record for a second.</p> <p>14 THE VIDEOGRAPHER: Stand by.</p> <p>15 11:31. We are off the video</p> <p>16 record.</p> <p>17 (Brief recess.)</p> <p>18 THE VIDEOGRAPHER: 11:41.</p> <p>19 We are on the video record.</p> <p>20 MS. GEMAN: I'm going to</p> <p>21 introduce two exhibits. What's</p> <p>22 marked as Exhibit 1 is entitled</p> <p>23 the Amended Notice to Take</p> <p>24 Videotaped Oral Deposition.</p>
<p style="text-align: right;">Page 119</p> <p>1 therapeutic if you're able to catch a</p> <p>2 polyp. The data actually isn't</p> <p>3 completely mature to see if it's making</p> <p>4 people live longer.</p> <p>5 But, you know, it's the</p> <p>6 practice that is the presumption. Colon</p> <p>7 cancer rates are ever so slightly</p> <p>8 decreasing, although it's interesting</p> <p>9 that there are so, so, so many</p> <p>10 colonoscopies.</p> <p>11 I would like to think that's</p> <p>12 true. I don't have the -- I haven't read</p> <p>13 any updated studies on whether or not</p> <p>14 that's confirmed. It's actually a little</p> <p>15 bit more in the gastroenterology</p> <p>16 literature.</p> <p>17 Q. And the risk of colon</p> <p>18 cancer -- I'm sorry. Strike that.</p> <p>19 The risk of perforation from</p> <p>20 a colonoscopy have gone down since 1987,</p> <p>21 correct?</p> <p>22 A. I don't know that data.</p> <p>23 That's really -- I don't know went down.</p> <p>24 I know the general perforation risk. I</p>	<p style="text-align: right;">Page 121</p> <p>1 (Document marked for</p> <p>2 identification as Exhibit</p> <p>3 Teitelbaum-1.)</p> <p>4 MS. GEMAN: What's been</p> <p>5 marked as Exhibit 3 -- we'll come</p> <p>6 back to 2 -- is Defendants'</p> <p>7 Responses and Objections to</p> <p>8 Plaintiffs' Notice of Videotaped</p> <p>9 Deposition of Dr. Ursina</p> <p>10 Teitelbaum.</p> <p>11 THE WITNESS: Ursina.</p> <p>12 MS. GEMAN: Ursina, I</p> <p>13 apologize.</p> <p>14 (Document marked for</p> <p>15 identification as Exhibit</p> <p>16 Teitelbaum-3.)</p> <p>17 MS. GEMAN: Madam Court</p> <p>18 Reporter, please hand the witness</p> <p>19 the exhibits.</p> <p>20 BY MS. GEMAN:</p> <p>21 Q. Do you recognize, Doctor,</p> <p>22 what's been marked as Exhibit 1 and</p> <p>23 Exhibit 3?</p> <p>24 A. I see Exhibit 1. And that's</p>

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1 3. And there's 2. And that's 4.
 2 I think I didn't read
 3 through Exhibit 3. But I think I've seen
 4 the document or read through it briefly.
 5 But, you know, yes.
 6 Q. Please turn to Page 3 of
 7 Exhibit 1.
 8 A. Yes.
 9 Q. Do you see where it says,
 10 "Document requests"?
 11 A. Yes.
 12 Q. Did you look for documents
 13 in response to this request?
 14 A. Every single number.
 15 Q. Do you have a formal
 16 retention letter?
 17 A. No.
 18 Q. Do you know if RX Pro has a
 19 formal retention letter?
 20 A. I don't know.
 21 Q. Is part of the income that
 22 you're earning in connection with this
 23 engagement going to RX Pro?
 24 A. I believe so, yeah. I think

Page 123

1 so.
 2 Q. So you have an hourly rate
 3 and a fee schedule, correct?
 4 A. Yes.
 5 THE VIDEOGRAPHER: I
 6 apologize. You're hitting the
 7 microphone. Yeah. Thank you.
 8 BY MS. GEMAN:
 9 Q. Is it that you're then
 10 giving part of what you receive over to
 11 RX Pro or do you understand that they are
 12 separately billing?
 13 A. I am asked to send my bills
 14 to them. And I do that, and then they
 15 pay me. And I assume that they are
 16 adding on a fee.
 17 Q. So how much per hour are you
 18 personally getting?
 19 A. I'm personally getting \$500
 20 an hour.
 21 Q. And is it different for
 22 testimony?
 23 A. That's like today?
 24 Q. Yes.

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1 A. I think that's \$750 an hour.
 2 Q. Okay. Any other hourly
 3 rates that you personally are getting?
 4 A. No.
 5 MS. GEMAN: I'm going to now
 6 introduce as Exhibit 2 some
 7 invoices.
 8 (Document marked for
 9 identification as Exhibit
 10 Teitelbaum-2.)
 11 MS. GEMAN: If the court
 12 reporter would hand them over to
 13 you.
 14 BY MS. GEMAN:
 15 Q. You have them?
 16 A. Yes.
 17 Q. So Doctor, what's been
 18 marked as Exhibit 2 is the three invoices
 19 that were provided to me. And my first
 20 question is, do you recognize this packet
 21 of three invoices?
 22 A. I've actually never seen
 23 this packet.
 24 Q. So there is a different

Page 125

1 document that you provide to RX Pro?
 2 A. Yes.
 3 Q. And that document itemized?
 4 A. Yes.
 5 Q. How many invoices have you
 6 provided to RX Pro?
 7 A. I think three.
 8 Q. Do you recall when the first
 9 one was?
 10 A. I can't remember if it was
 11 December or early January.
 12 Q. And the second?
 13 A. Was probably maybe
 14 mid-January.
 15 Q. And the third?
 16 A. I don't know the exact date.
 17 I'm guessing it was end of January or
 18 early February.
 19 Q. Have you been paid yet for
 20 all the work that you've done in this
 21 case, other than today?
 22 A. Yes, I have.
 23 Q. So there was -- you have
 24 already been paid for your deposition

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1 prep time?

2 A. I haven't been paid for any

3 time since -- I have another invoice to

4 submit. I waited until after today.

5 I don't know when the last

6 check came exactly.

7 Q. Oh, I see. So you've been

8 paid for the invoices for which you've

9 already submitted?

10 A. These are the only ones. I

11 don't know if there are dates on them.

12 Q. How much is current invoice

13 for, the one that you have not yet

14 submitted?

15 A. So it is probably about ten

16 hours, and then I would add today.

17 Q. And that's deposition prep

18 time and then the deposition today will

19 be added?

20 A. And I -- you know, I had

21 to -- yes. And the transportation.

22 Yeah.

23 Q. Okay. If you could look at

24 the first page of this invoice.

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1 Is this a standard retainer

2 of yours?

3 A. I haven't seen this. I

4 didn't -- explain what a retainer is.

5 Q. Oh, do you see under

6 description, it said retainer?

7 A. Yes.

8 Q. So I -- is this -- is this

9 an invoice for a retainer?

10 A. I don't think I have a

11 retainer. I don't know.

12 Can you just say what a

13 retainer is again? I just have an hourly

14 rate.

15 Q. I understand. Sometimes

16 experts will say, I have an hourly rate,

17 but to get us going, please send us a

18 retainer of X, and then that gets billed

19 against essentially?

20 A. I've only sent hours.

21 That's all I've sent.

22 Q. Okay. So can you please

23 turn to the second page.

24 A. Wait one second. For him,

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1 I'm going to take the chain off. Yes.

2 Q. Do you see in this invoice

3 dated 1/12/2022 that it indicates that

4 you had billed 51 hours?

5 A. Yes.

6 Q. Does that seem accurate?

7 A. Yes. I -- and you'll see

8 that in my expert letter. I reviewed --

9 and that's what the printing cost is

10 actually.

11 I reviewed all of the expert

12 letters from defense and plaintiff. My

13 living room looked like a minefield. And

14 I actually reviewed every one of them.

15 It was so long that that's why I had to

16 print, because I'm still a bit married to

17 paper, and I couldn't really do all the

18 reading on the computer.

19 So that took some time, in

20 addition to the literature search, which

21 took a fair amount of time, and then

22 writing the expert letter.

23 Q. Did you write the expert

24 report?

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1 A. I did.

2 Q. Were you provided any

3 language by others?

4 A. The only language that I

5 incorporated was that -- what is it

6 called -- Rule 26. That wasn't familiar

7 to me. But I think that's sort of an

8 expert letter or legal definition maybe.

9 Q. But everything else was

10 written by you, other than the --

11 essentially the intro?

12 A. Well, it wasn't really the

13 intro. It was a little blurb, but yes.

14 Q. Okay. And does this

15 51 hours reflect time spent writing the

16 report, as well as engaging in medical

17 review?

18 A. This 51 hours, the reason

19 it's longer, is I read, in addition to my

20 literature search, and the time I spent

21 writing, it did take some time to work

22 through those very dense expert letters.

23 Q. I appreciate that. What I'm

24 trying to understand is, does this

Page 130

1 51 hours include the time you spent
2 writing the report?
3 A. Yes.
4 Q. Okay. Do you have a sense
5 of how much time was spent writing the
6 report?
7 A. I'm trying to think.
8 Maybe -- because I kept going back and
9 looking at references.
10 It's hard to tell.
11 MR. KUM: Just ballpark it
12 if you can.
13 THE WITNESS: It was all
14 kind of entwined. Probably 12 to
15 15 hours. It's a lot of time.
16 Because my process is I
17 write, I research, I write, I
18 research.
19 And then whenever you look
20 things up, you find more things.
21 And then I go back.
22 I can tell you that it was
23 my entire winter break since
24 Omicron ruined our family travel

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1 plans. So it was a lot of time.
2 BY MS. GEMAN:
3 Q. So you spent between a half
4 an hour and 40 minutes writing each page?
5 A. I can't really process it
6 that way. I mean, some of it was
7 saying -- you know, the substantive
8 things took time. Again, it's -- I was
9 saying before, I'm a pretty fast typist
10 once I get going.
11 So there was both research
12 and writing and reviewing. I'm -- I was
13 a history major, so I really like looking
14 at primary documents and trying to
15 understand the literature.
16 Q. And the third page of this
17 document, Exhibit 2, indicates 18 and a
18 half hours?
19 A. Mm-hmm.
20 Q. This time there's a
21 breakdown of detail.
22 Do you see that?
23 A. Yes.
24 Q. Do you know why there isn't

Page 132

1 a breakdown of detail on the previous
2 page?
3 A. I'm not sure. I broke down
4 detail, I think, with each time. But I
5 can't remember for sure.
6 Q. Do you know why the RX Pro
7 provided detail on one invoice and not
8 another?
9 A. I don't know.
10 Q. Did anybody edit your
11 report?
12 A. I had, with typos and
13 grammar.
14 Q. You said I had with typos?
15 A. There was help with editing
16 for typos and grammar. But the substance
17 was mine.
18 Q. Help from RX Pro?
19 A. No. Help from -- I can't
20 remember who did it.
21 Q. Was it someone that you work
22 with?
23 A. It was someone on the team,
24 and they were, you know, capitalize this,

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1 a semicolon is better.
2 Q. You mean the legal team?
3 A. Yeah. What is CLIA? It was
4 like if I had an abbreviation. It was,
5 like, grammar.
6 Q. Okay. Fair enough. And if
7 we could -- and I'm sorry. You indicated
8 that you do have another invoice to be
9 sent, correct?
10 A. Yes. After today.
11 Q. Okay. So let's, if we could
12 now, turn back to the document requests.
13 A. Mm-hmm.
14 MR. KUM: It's Exhibit 1.
15 THE WITNESS: Yes. Mm-hmm.
16 BY MS. GEMAN:
17 Q. Now, earlier you indicated
18 you read Dr. Kaplan's deposition
19 transcript, correct?
20 A. Yes.
21 Q. All right. Did you read any
22 other documents in preparation for this
23 deposition other than those listed in
24 your report?

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1 MR. KUM: Asked and
2 answered.
3 You can go ahead.
4 MS. GEMAN: It may have
5 been. I just don't remember.
6 THE WITNESS: I read and
7 listed the expert letters from
8 both plaintiff and defense.
9 I read Dr. Kaplan's expert
10 letter. I read his deposition.
11 And I read my own letter --
12 BY MS. GEMAN:
13 Q. Sure.
14 A. -- before I came here.
15 Q. Did you rely on any of the
16 expert reports that you reviewed in
17 forming your opinions?
18 A. Actually, not at all. They
19 were so dense, really, that it would not
20 have informed my opinion.
21 And again, you know, a lot
22 of it boiled down to whether or not NDEA
23 and NDMA are a carcinogen or not. And
24 that did not at all inform my review of

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1 the medical monitoring protocol.
2 Q. Do you have an opinion about
3 whether NDMA or NDEA are carcinogens?
4 MR. KUM: Objection.
5 Outside the scope.
6 THE WITNESS: I don't think
7 it's really germane to my review
8 of Dr. Kaplan's medical
9 monitoring, again, noting that
10 known carcinogens exposure does
11 not change task force
12 recommendations.
13 BY MS. GEMAN:
14 Q. Do you have an opinion about
15 whether NDMA or NDEA are carcinogens?
16 A. I have no opinion.
17 Q. And have you authored any
18 materials about medical monitoring?
19 A. Of medical monitoring -- oh,
20 like a list of testing, screening?
21 Q. Sure.
22 A. I haven't.
23 Q. Have you authored any
24 materials about cancer screening?

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1 A. Cancer screening, like
2 specific cancers or -- I have not.
3 Q. And how did you select the
4 articles that you reviewed and that were
5 cited in your report?
6 A. I'm using the Penn
7 biomedical library, interrogated PubMed.
8 And once or twice I had to go to OVID.
9 And I had one document that I had to have
10 them -- that was sort of an archived
11 document because of age. I had to have
12 them retrieve it for me. And then I
13 could look at it.
14 Q. Was that the 1993 article?
15 A. That's the Ekstram.
16 Q. The what?
17 A. The author is Ekstram.
18 Q. Okay. Was that about
19 colonoscopies?
20 A. That was about Swedish
21 population, looking at cancer rates in, I
22 think, metal and rubber workers of
23 inhaled.
24 Q. Did you look for contrary

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1 information?
2 A. I really focused on the
3 screening protocols. I read every
4 document that I thought was updated and
5 relevant.
6 Q. So take an example of
7 anxiety caused by tests. Did you read --
8 did you look for both articles that said
9 yes, testing causes anxiety or no,
10 testing doesn't cause anxiety?
11 A. So in truth, it is a very
12 sparse literature. There isn't a lot of
13 information. So what I look for and have
14 always looked, if there seems to be a
15 predominate author who is an expert in
16 the field -- and you'll see that when you
17 pull up, some names come up over and over
18 again, which suggests to me that's really
19 their main area of study.
20 So I read those. And, you
21 know, anything that seems pertinent to
22 the topic that's more recent.
23 Q. So just to be more precise
24 though, did you look for contrary

Page 138

1 information? So if you were --
2 A. So I didn't not look for. I
3 put in the topic, and I looked at the
4 results.
5 Q. And how did you determine
6 who, in your view, seemed to be the
7 predominate author?
8 A. For which topic?
9 Q. For any topic.
10 A. Again, it was number of
11 citations.
12 Q. So in your view, if an
13 article said testing doesn't -- just
14 picking any example, testing doesn't
15 cause anxiety, such that it's -- strike
16 that.
17 If an article said the cost
18 of anxiety does not outweigh the benefits
19 of the test, and another article said the
20 opposite, do you think the one with more
21 citations wins?
22 A. I would probably list that
23 as a controversial area.
24 I definitely welcome all

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1 sides.
2 Q. And are there documents that
3 you read that you did not put in your
4 report?
5 A. If I didn't cite the source,
6 I read -- in my initial look, I looked at
7 Wikipedia to find out about the way the
8 valsartan impurity -- the date -- to kind
9 of get the dates and a context, because I
10 wasn't familiar with it.
11 I have looked at the United
12 States Preventive Task Force website.
13 And I -- you know, just to understand the
14 process.
15 Q. That's helpful. So other
16 than the wiki background and the website,
17 are there other materials that you looked
18 at that you did not cite in your report?
19 A. I'm not really sure. I'm
20 more of an overciter than an underciter
21 because I never want to plagiarize. So I
22 always try to give credit, knowing how
23 much time and effort people put into
24 their work.

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1 So I don't really know how
2 to answer that. But knowing how I do it,
3 I would imagine not.
4 Q. So sitting here now, you
5 can't think of any articles that you
6 reviewed but you didn't put in the
7 article -- put in the report? Excuse me.
8 A. There were so many -- you
9 know, I didn't open every -- you know, it
10 gives you a hundred options. I may have
11 looked through titles to see if it was
12 relevant. But I didn't open every
13 article.
14 Q. That's helpful.
15 Of the ones that you did
16 open and review, are they all cited in
17 your report?
18 A. I hope so.
19 Q. Okay.
20 MS. GEMAN: Let's introduce
21 your report.
22 Does anybody need a copy of
23 it?
24 BY MS. GEMAN:

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1 Q. Doctor, has -- is what's
2 been marked as Exhibit 4 the report that
3 you wrote?
4 A. Yes.
5 (Document marked for
6 identification as Exhibit
7 Teitelbaum-4.)
8 BY MS. GEMAN:
9 Q. Thank you. Is that your
10 signature on Page 25?
11 A. It's my electronic
12 signature.
13 Q. And it's dated January 12th;
14 is that correct?
15 A. Yes.
16 Q. And the work you did on this
17 report, as you earlier indicated, was
18 between approximately December 27th and
19 January 12th?
20 A. I think I -- well, I guess
21 the --
22 Q. Let me withdraw the
23 question. Your hesitancy reminds me that
24 my question was poor.

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1 I think you testified that
2 you started working at some point in
3 mid-December; is that correct?
4 A. Yeah, because I did a lot
5 of -- again, reading all those -- those
6 really thick documents took some time.
7 And that was more to -- to your point, to
8 understand both sides and to get some
9 context.
10 Q. And so what is Rule 26 of
11 the Federal Rules of Civil Procedure?
12 This was the point that you mentioned
13 earlier?
14 A. Yeah. I think it just
15 speaks to how I give my opinions.
16 Q. So will you please identify
17 for me any facts or data that the
18 attorneys provided to you and that you
19 considered in forming your opinions?
20 A. I -- only things that the
21 attorneys gave me were Dr. Kaplan's
22 letter and then later his deposition.
23 And again, I was very democratic in
24 reviewing all of the provided expert

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1 letters from plaintiffs and defendants.
2 And actually, this sort of
3 Rule 26 was repeated over and over again.
4 And that's quite honestly where I learned
5 about it and saw that it might be a
6 required element.
7 And I put it in, but then
8 confirmed that that was appropriate.
9 Q. Can you identify for me any
10 assumptions that the attorneys provided
11 and that you relied on in forming your
12 opinions?
13 A. They actually really just
14 wanted my opinions. There were no
15 assumptions. They gave me the document
16 and asked me to address it, which, you
17 know, that was my independent.
18 Q. Okay. And you state that --
19 in the second sentence of the second
20 paragraph, that, "Each of the opinions
21 offered in this report are given to a
22 reasonable degree of medical probability
23 and/or certainty."
24 Did you write that sentence?

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1 A. I wrote it. But again, I
2 think this was the language that I had
3 seen in the others.
4 I don't know -- I don't know
5 if that applies to the Rule 26 or not. I
6 put it in there.
7 Q. What is the meaning of
8 reasonable degree of medical probability
9 and/or certainty?
10 A. I would say that, based on
11 my -- you know, my impression, based on
12 my 20 years of practice, my extensive
13 experience with clinical care and again,
14 my review of the literature.
15 Q. So which -- which opinions
16 -- strike that.
17 About which opinions do you
18 assign probability as opposed to
19 certainty?
20 MR. KUM: Objection. Vague
21 and ambiguous.
22 THE WITNESS: I am certain
23 that I am extremely uncomfortable
24 with Dr. Kaplan's medical

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1 monitoring protocol.
2 I guess the only
3 uncertainty -- I'm trying to think
4 what I'm uncertain about. Because
5 I'm extremely certain about that
6 and would love to address it.
7 Let me think.
8 BY MS. GEMAN:
9 Q. So with which opinions are
10 you giving a reasonable degree of
11 probability rather than certainty?
12 A. I guess, you know, I know --
13 MR. KUM: Objection.
14 Assumes facts not in evidence.
15 THE WITNESS: I don't know
16 what the -- it's very hard.
17 There's a lot of opinions to parse
18 out. I'm not sure.
19 BY MS. GEMAN:
20 Q. Can you name any?
21 A. I guess I'm not certain how
22 many pills the patients took. I don't
23 know that information. I actually don't
24 know how many there were. I'm assuming

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1 it's a large number. I'm assuming there
2 are cardiac patients.
3 You know, those are not
4 certainty, because I don't have
5 information about the patient
6 specifically. But I'm assuming it's
7 about those patients.
8 Q. And what's your
9 understanding of how much contaminated
10 product was in the valsartan that the
11 patients ingested?
12 MR. KUM: Objection.
13 Outside the scope.
14 Don't guess.
15 THE WITNESS: Yeah, I --
16 again, I read it for context.
17 It's not really relevant to the
18 mission that I was set forward to
19 review Dr. Kaplan's medical
20 monitoring program.
21 BY MS. GEMAN:
22 Q. So sitting here now, you
23 just don't know how much nitrosamine was
24 in the valsartan; is that correct?

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1 A. I don't.
2 Q. You refer us to Exhibit A,
3 if we can turn to that on Page 27.
4 A. Yes.
5 Q. And a couple of -- some of
6 these individuals wrote more than one
7 report. Do you know which reports you
8 read?
9 A. I had one report from each.
10 Q. One report from each. Was
11 the report from Janice Britt about
12 general causation or medical monitoring?
13 A. There were a lot, and it was
14 a long time ago. I'm not certain.
15 Q. Do you know which of these
16 experts of defendants have subsequently
17 been withdrawn or stricken as not
18 satisfying the gatekeeper functions?
19 Let me rephrase that.
20 Do you know which of these
21 experts of defendants have subsequently
22 been withdrawn or stricken by the court?
23 A. I know Daniel Catenacci
24 was -- I don't know if it's stricken or

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1 withdrawn.
2 Q. What's the basis of that
3 knowledge?
4 MR. KUM: Again, without
5 disclosing specific conversations
6 that you've had with counsel.
7 THE WITNESS: I'm assuming I
8 was forwarded some news reports
9 from colleagues, you know, about
10 an SEC indictment.
11 I don't know for sure that's
12 what it was. But that's probably
13 a pretty good guess.
14 BY MS. GEMAN:
15 Q. And did you rely on his
16 opinions in forming your own?
17 A. I did not.
18 Q. And do you know any of these
19 individuals listed?
20 A. So I do not know
21 Dr. Etminan. I do not know Dr. Hecht. I
22 do not know Dr. Panigrahy. I do not know
23 Dr. Madigan. I do not know Dr. Lagana.
24 I have not met Dr. Catenacci in person.

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1 He was a fellow some years after I left.
2 I have seen him speak.
3 I do not know Dr. Bottorff.
4 I do not know Dr. Britt.
5 I know of Dr. Chodosh
6 because he is a very esteemed physician
7 scientist, among the best in -- I mean
8 amazing. And I don't know that he would
9 even know me. He -- there are some silos
10 at big institutions, especially with lab
11 scientists. He would probably recognize
12 my name.
13 But he mostly does
14 translational research with the breast
15 group, which is a separate subspecialty
16 group.
17 I don't know Dr. Flack. I
18 don't know how this to say this next
19 person's name, but I don't know him. I
20 don't know Dr. Gibb. I don't know
21 Dr. Johnson. And I do not know Dr. Wei.
22 Q. And you also reviewed -- and
23 you said this before -- the task force
24 guidelines, correct?

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1 A. Yes.

2 Q. Did you review any other

3 guidelines?

4 A. I briefly looked at -- and

5 again, these are actually a little bit

6 more specific to patients that have

7 already been diagnosed with cancer.

8 So the National

9 Comprehensive Cancer Network, which I

10 looked at some of the subspecialty

11 guidelines, like hepatology and

12 gastroenterology.

13 Those were sort of more

14 relevant to when I was assessing each

15 item on Dr. Kaplan's monitoring list.

16 That's what I can think of sitting here.

17 Q. Did you look at the ASCO?

18 A. ASCO. I did not.

19 Q. You did not.

20 A. ASCO?

21 Q. Yes.

22 A. I didn't look -- I mean, I

23 looked relative to referring high risk

24 patients. I just confirmed because,

Page 151

1 since I have the good fortune of being in

2 an academic center, I just wanted to be

3 sure.

4 You know, they put out these

5 guidelines to standardize care and make

6 sure all care is of a good level. So I

7 made sure that my practice was the same.

8 I mean, I look at NCCN

9 guidelines every day --

10 Q. Why?

11 A. -- multiple times a day.

12 Q. Why?

13 A. Because you always -- again,

14 it's safety and standard of care. And

15 you want to make sure that you're within

16 the consensus recommendations, not only

17 because you want the best care for the

18 patient, because it may inform insurance

19 coverage, unfortunately, of a recommended

20 treatment.

21 So, you know, I'm sort of --

22 check, check, double-check all the time,

23 if I -- you know, every prescription,

24 everything I put my name to, I

Page 152

1 double-check.

2 Q. So NCCN is part of the

3 consensus of standard of care?

4 A. National Comprehensive

5 Cancer Network puts out these guidelines.

6 And it's interesting, I don't know --

7 like, you know, you have branch points

8 from diagnosis, what stage, what the

9 options are. Obviously it's personalized

10 to the patient, both in terms of their

11 individual cancer and their fitness

12 status.

13 You know, I don't think it

14 was originally designed that way. But

15 unfortunately, insurance tends to follow

16 the guidelines. So I don't want patients

17 to get bills. So I'm careful to review

18 them.

19 Q. So is it NCCN part of the

20 consensus standard of care?

21 A. It is a national

22 comprehensive cancer -- that puts out

23 guidelines, that help -- that's part of

24 the standard of care.

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1 Q. Is it a respected

2 organization?

3 A. Very.

4 Q. Did you review their

5 screening guidelines?

6 A. I think I did. And I

7 remember that they -- again, these are

8 generally in the setting of cancer.

9 They did have some screening

10 guidelines. I can't remember exactly.

11 They were not -- it's hard to say because

12 the task force guidelines are for

13 asymptomatic patients in the primary care

14 setting.

15 The NCCN were a little more

16 nuanced, but I don't think is the

17 national standard, I wouldn't say is the

18 national standard for asymptomatic

19 patients in the primary care setting.

20 Q. To the extent NCCN and

21 U.S. --

22 A. We'll just call it the task

23 force.

24 Q. Thank you. And by task

Page 154

1 force, we mean the USPTF?
2 MR. KUM: USPSTF. You
3 missed an S.
4 THE WITNESS: S. Screening.
5 S is screening.
6 MR. KUM: You missed an S.
7 BY MS. GEMAN:
8 Q. I missed the S.
9 A. Preventive screening task
10 force.
11 Q. I apologize.
12 So to the extent that the
13 USPSTF, i.e., the task force, and NCCN
14 differ, do you think one is right and one
15 is wrong?
16 A. I would put that
17 differently. Every subspecialty group
18 comes out with it's sub -- you know, it's
19 consensus guidelines. You know,
20 hepatology, thoracic, pulmonary, they may
21 have them. That doesn't mean that they
22 are -- and it's generally different,
23 because these are patients that have been
24 referred to them.

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1 It is not the -- for
2 example, hepatology, if they have a
3 patient referred to them with known
4 cirrhosis, will have a different
5 guideline. It's usually
6 disease-specific.
7 Unfortunately, the way that
8 we know what the national standard is, is
9 what Medicare will cover.
10 Medicare will cover the task
11 force recommendations, and regular
12 insurance quickly follows. And what I
13 would say also again -- I mentioned we
14 have electronic health records that
15 prompt us to what the standardized
16 evidence-based recommendations are from
17 the task force.
18 This comes from the
19 Department of Health & Human Services.
20 And the task force recommendations are
21 what we are prompted for.
22 And I am not certain, I
23 would actually suspect not, that if you
24 follow different guidelines, it would be

Page 156

1 covered by any insurance.
2 Q. If you could please turn to
3 your CV, which is Exhibit B of your
4 report. It's within the report itself.
5 A. Okay.
6 Q. And I noted also that your
7 counsel provided a slightly more updated
8 that included abstracts?
9 A. Yeah, I thought that would
10 be more complete. It's sort of in
11 oncology. You know, you don't always put
12 your abstracts on. But I thought for
13 completeness, that would be appreciated.
14 Q. So is the with the inclusion
15 of the abstracts, is your CV complete?
16 A. Yes.
17 Q. Let's turn to, please,
18 Page 4 of your report.
19 MR. KUM: Are you marking
20 this as an exhibit?
21 MS. GEMAN: It's already --
22 well, it's within the -- I mean,
23 we received it all as one.
24 MR. KUM: Oh, that's right.

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1 Okay.
2 MS. GEMAN: Yeah, we're
3 happy to -- I don't have it
4 printed. But I'm happy to mark
5 the more updated CV if you wish.
6 Okay.
7 Actually, this is -- let's
8 go off the record and do a brief
9 lunch break now if that's okay
10 with you, Doctor.
11 THE VIDEOGRAPHER: 12:20.
12 We are off the record.
13 - - -
14 (Whereupon, a luncheon
15 recess was taken.)
16 - - -
17 THE VIDEOGRAPHER: 1:06. We
18 are on the video record.
19 - - -
20 CONTINUED EXAMINATION
21 - - -
22 BY MS. GEMAN:
23 Q. Good afternoon, Doctor.
24 Sitting here now, is there

Page 158

1 anything in your report that you would
2 like to change?
3 A. No.
4 Q. Could I ask you to please
5 turn to the last page?
6 A. Of the report?
7 Q. Yes.
8 A. Can you tell me which page?
9 Q. Yes. I'm sorry. Page 24.
10 Do you see that? Are you on Page 24?
11 A. I am. I hope your page and
12 my page match.
13 Q. Well, I'm going to read you
14 the first sentence of the second-to-last
15 paragraph.
16 "It is not clear from any of
17 the data I have reviewed on valsartan
18 that nitrosamine exposure increases the
19 pretest probability of developing any
20 cancer in the human patients and
21 therefore merits changes in validated
22 screening tests and intervals."
23 Did I read that correctly?
24 A. Yes.

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1 Q. Does this -- earlier today
2 you testified that you were offering no
3 opinion on whether nitrosamines caused
4 cancer; is that correct?
5 A. I don't -- I don't know if
6 it does or it doesn't.
7 Q. All right. And are you
8 making a causal statement here that --
9 namely, that your review of the expert
10 reports in this case leads you to infer
11 that nitrosamine exposure does not cause
12 cancer?
13 A. So I'm not a causal expert,
14 as I mentioned before.
15 I read both defendant and
16 plaintiff, sort of very different. And
17 so I wasn't sure. I think it's true that
18 I don't know from the data that it does
19 or doesn't. So that's sort of that
20 statement.
21 But again, no exposure
22 merits changing the national guidelines
23 put out by the task force.
24 So I can't speak to changing

Page 160

1 those guidelines based on whether or not
2 it is -- whether or not it is
3 carcinogenic or not. I can't -- I
4 wouldn't change the guidelines.
5 And to me, what is reflected
6 in that sentence is, I don't know.
7 Q. All right. So but whether
8 it's appropriate for medical monitoring
9 to be ordered in this case is an entirely
10 separate question from whether the
11 general population guidelines are
12 formally changed. Do you understand
13 that?
14 MR. KUM: Objection. Vague
15 and ambiguous.
16 THE WITNESS: Yeah, can you
17 repeat or re --
18 BY MS. GEMAN:
19 Q. Whether it's appropriate for
20 medical monitoring to be ordered in this
21 case is an entirely separate question
22 from whether the general population
23 guidelines are formally changed.
24 Do you understand that?

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1 MR. KUM: Same objections.
2 THE WITNESS: There's no
3 indication to change guidelines of
4 screening for asymptomatic
5 patients based on any exposure.
6 BY MS. GEMAN:
7 Q. What does that mean?
8 A. It means that whether or not
9 this is a carcinogen would not change my
10 opinion.
11 Q. So there's no amount of sort
12 of danger from the contaminated medicine
13 that the class members took that would
14 cause you to believe that any screening
15 is appropriate?
16 A. I can't speak to that. I
17 expect that the task force would review
18 confirmed human carcinogens. And whether
19 or not that would change it, is actually
20 completely in the task force hands. That
21 is not to me.
22 But what I have read and
23 reviewed is the only exposure that
24 changed any of the recommendations was

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1 20 years of tobacco between ages 55 and
 2 80.
 3 And there are lots of known
 4 human carcinogens, including asbestos,
 5 radon exposure, that are confirmed, that
 6 did not inform the task force
 7 recommendations. It did not meet the
 8 magnitude of harm, magnitude of benefit
 9 definition.
 10 Q. So I'm asking a slightly
 11 separate question, which is that, is
 12 there any amount of danger from the --
 13 danger meaning carcinogenic danger, from
 14 the contaminated medicine that the class
 15 members took that would cause you to
 16 believe that any screening is
 17 appropriate, whether or not it is
 18 accompanied by a change in the task
 19 force?
 20 MR. KUM: Asked and
 21 answered.
 22 THE WITNESS: I can't really
 23 speak to that.
 24 BY MS. GEMAN:

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1 Q. You can't answer that
 2 question?
 3 A. I don't know -- I don't know
 4 what the -- you know, again, right now
 5 it's not a known human carcinogen. I
 6 don't know really anything about the
 7 dose, kinetics, or -- I have no idea.
 8 Q. So if I ask you to assume
 9 just for purposes of this question that
 10 it is a known human carcinogen, or that
 11 it is a carcinogen, is there any amount
 12 of danger, carcinogenic danger to the
 13 class that would prompt you to conclude
 14 that screening is appropriate whether or
 15 not accompanied by a change in the task
 16 force?
 17 MR. KUM: Incomplete
 18 hypothetical. You can answer, if
 19 you can.
 20 THE WITNESS: This doesn't
 21 really address the task I was
 22 given to evaluate the tests that
 23 were put forth.
 24 And I -- you know, to your

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1 point, they were suspecting that
 2 tobacco usage was carcinogenic for
 3 years. And they didn't change the
 4 guidelines until a study came
 5 forth, randomized control trial,
 6 New England Journal, that was then
 7 reviewed by the task force, and
 8 one of the first major adjustments
 9 was put forth.
 10 So I can't speak to whether
 11 or not it would influence. It is
 12 quite honestly too hypothetical.
 13 BY MS. GEMAN:
 14 Q. Sitting here today, you
 15 can't answer that question?
 16 A. Based on what I know of
 17 screening and how exposures are handled,
 18 I do not think it would change the
 19 guidelines. And I do not think that the
 20 medical monitoring put forth would prove
 21 of more benefit than harm.
 22 I think the medical
 23 monitoring program put forth by
 24 Dr. Kaplan is extraordinarily harmful and

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1 dangerous to an asymptomatic patient.
 2 Q. What screening would you
 3 suggest for patients who were exposed to
 4 dangerous amounts of nitrosamine in their
 5 valsartan due to culpable behavior of the
 6 defendants, which is the assumption that
 7 I'm offering for purposes of this
 8 question?
 9 A. I --
 10 MR. KUM: Objection.
 11 Assumes facts not in evidence.
 12 Incomplete hypothetical.
 13 You can answer.
 14 THE WITNESS: I don't know
 15 of any exposure right now that
 16 changes the guidelines, including
 17 radon, asbestos, and others
 18 currently. I don't -- I don't
 19 know. That is the premise of my
 20 opinion.
 21 BY MS. GEMAN:
 22 Q. If Galleri were available,
 23 would you use it?
 24 A. Galleri?

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1 Q. Galleri.
2 A. So it's -- it's so
3 interesting. So I would not use it
4 outside of the context of a clinical
5 trial. Frankly, I'm not sure how
6 Dr. Kaplan is ordering it since it's not
7 FDA approved. It has a spectacular
8 advertising campaign. I have patients
9 ask me about it all the time.
10 It would not be covered by
11 insurance. It is not FDA approved. And
12 it is particularly not validated in
13 screening. The only studies today are
14 observational. They are not even fully
15 prospective.
16 I suspect sometimes these
17 companies come to particularly private
18 practice offices. They're not allowed in
19 ours. And they give them some free ones
20 to kind of encourage interest and
21 enthusiasm for ordering them.
22 I don't know how he could
23 order it and have an insurance pay. So
24 that's what I suspect is happening.

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1 Q. So I'm sorry. Are you
2 suggesting that Dr. Kaplan recommended
3 this test because, in your imagination,
4 they may have gone to his office?
5 A. I have no idea how -- you
6 know, they come in these boxes. You have
7 to either order them or oftentimes the
8 reps will deliver them. He specifically
9 stated in his deposition that he ordered
10 them a few times.
11 They often give them gratis
12 because they want, in the future, the
13 doctors to order them. So I don't even
14 know how he gets the kit. It's only FDA
15 approved that -- or potentially
16 commercially available -- not FDA
17 approved. It is not FDA approved. But
18 it is only commercially available in New
19 York, based on what I read.
20 So I don't even know how he
21 had access to the test.
22 Q. Well, you didn't cite the --
23 anything for the proposition that it's
24 only commercially available in New York.

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1 A. It's in my letter.
2 Q. Can you point to the cite?
3 A. Sure. Happy to.
4 Q. It's probably on Galleri,
5 Galleri -- Galleri, Galleri. It's on
6 Page 20 -- 21.
7 A. So Number 1, these tests are
8 not FDA approved. Galleri has --
9 Q. Excuse me. I'm going to ask
10 you to answer my question. What is the
11 cite for your statement that it's not
12 commercially available outside of New
13 York? There are no citations here.
14 A. I might have gotten it from
15 the -- I looked at the website. I can't
16 say for sure. I did look at the website
17 of the company. I didn't cite the
18 website.
19 Q. So does this refresh your
20 recollection about other documents that
21 you looked at but did not cite in your
22 report?
23 A. I'm not sure if a commercial
24 website for a product is a document. But

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1 I would add that to it then.
2 Q. What other websites did you
3 look at that you did not cite in your
4 report?
5 A. I think that's the only test
6 that I had looked up. I wasn't familiar
7 with it, and I wanted to see, you know,
8 how they were presenting it.
9 Q. Are you aware that Galleri
10 is available all across the country?
11 A. It depends on in what
12 context. I don't know how to order it.
13 I've never -- you know, I don't know how
14 it's done. It is not FDA approved. So
15 it would not be something that I would be
16 ordering.
17 Q. Do you have any -- you use
18 tests that aren't FDA approved
19 frequently, don't you?
20 A. No.
21 Q. None of your blood tests are
22 not FDA approved?
23 A. I mean, they're all done in
24 a CLIA lab. Which blood test do you

Page 170

1 mean?

2 Q. Name for me the blood test

3 that you use and tell me, please, which

4 are FDA approved as distinct from CLIA

5 certified?

6 MR. KUM: Objection. Vague

7 and ambiguous. Overbroad.

8 Outside the scope of her report.

9 But you can answer.

10 THE WITNESS: I mean, any

11 lab I order within the Penn system

12 is CLIA approved. It is a

13 CLIA-approved lab.

14 I've ordered Signatera,

15 which is FDA approved. I've

16 ordered Caris. I've ordered

17 Foundation.

18 The point is I don't order

19 tests for patients that I don't

20 think will get covered. I don't

21 do the free test from the company

22 strategy. I don't want a patient

23 to get a multithousand-dollar bill

24 for an uncertain indication.

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1 BY MS. GEMAN:

2 Q. So let's parse that, because

3 that's a different answer. So you do use

4 tests that are CLIA certified, correct?

5 A. Absolutely.

6 Q. Okay. And this Galleri is

7 or is not CLIA certified, to your

8 knowledge?

9 A. I don't know.

10 Q. And if I tell you that it's

11 CLIA certified, would that change your

12 disinclination to offer it to your

13 patients?

14 A. It's not FDA approved, and

15 the indication is uncertain. Every

16 time -- and I -- actually, this is a good

17 opportunity.

18 I looked at the data.

19 There's been a couple studies.

20 The biggest issue with the

21 Galleri GRAIL test as it pertains to

22 Dr. Kaplan's recommendation is, first of

23 all, the initial studies were validation

24 studies. If it says it's colon cancer,

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1 does the patient have colon cancer.

2 The other issue is it

3 depends to a degree how active the cancer

4 is, how many cell-free tumor DNAs in the

5 blood that can be measured.

6 And if you look at the most

7 updated data, for Stage I cancers, it

8 picks it up 14 percent of the time. For

9 Stage II, it picks up 40 percent of the

10 time.

11 For Stage III, it picks up

12 cancer 70 percent of the time. And for

13 Stage IV, it picks up cancer 90 percent

14 of the time.

15 And again, it speaks to the

16 activity of the tumor which is secreting

17 the cell-free DNA into the bloodstream.

18 My point with that is I

19 think Dr. Kaplan is hoping to find these

20 early stage cancers using this screening

21 tool. And there is poor evidence that it

22 is helpful in the early stages.

23 My concern would be, if a

24 patient got a false -- if it was false

Page 173

1 negative, again, they might discount any

2 symptoms or screenings that were relevant

3 to that cancer.

4 That is my biggest concern

5 with Galleri. It is not -- also, it's

6 not validated in the screening setting

7 for average risk or high risk. That

8 study is actually going on right now.

9 And the scientists -- the oncologists are

10 extremely good, George Fisher, Brad

11 Wolpin, top docs that are using this.

12 I just have to say, I love

13 the study design. So -- and it will take

14 years.

15 So they have two sets of

16 patients that are equivalent. One set

17 they do standard screening. The other

18 set they do Galleri in addition to

19 standard screening. And if a signal is

20 picked up on Galleri, they leave the

21 decision between the patient and their

22 doctor whether or not to pursue it.

23 And the key there is if a

24 patient, is -- for example, if they're

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1 not a surgical candidate because of their
2 cardiovascular disease or renal disease
3 or frailty or whatever reason, you don't
4 want to put someone through invasive
5 tests when you then can't act on the
6 findings.
7 Q. Dr. Teitelbaum, we're going
8 to have to keep coming back if you're not
9 going to answer my questions. And I will
10 use many of these answers as Exhibit A of
11 the motion to extend this deposition.
12 It is your job today to
13 answer the questions that I ask, not to
14 make speeches.
15 Do you understand that?
16 MR. KUM: Objection.
17 Argumentative. She did answer the
18 question. If you want to ask
19 another question, feel free.
20 BY MS. GEMAN:
21 Q. Do you understand that?
22 A. I would love to hear your
23 question again, if you think I didn't
24 address it. I'm happy to.

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1 Q. Good. Does it surprise you
2 that the test is CLIA certified?
3 MR. KUM: Asked and
4 answered.
5 THE WITNESS: That is not a
6 tough metric. Essentially every
7 lab in any sort of hospital or
8 clinic or LabQuest or Labcorp is
9 CLIA certified. They can't
10 process anything in the labs if
11 it's not CLIA certified.
12 BY MS. GEMAN:
13 Q. But you just said in your
14 earlier answer in support of the tests
15 that you order that they were CLIA
16 certified. So is it a different standard
17 for this test?
18 A. It's the standard for all
19 tests we order. I -- sometimes if we are
20 in -- doing a clinical trial, we just
21 have to apply for a CLIA certification to
22 make sure the test is considered valid.
23 But essentially anything
24 that I order at my hospital is CLIA

Page 176

1 certified.
2 Q. So contrary to your view in
3 your report, the test is CLIA certified.
4 It is available outside of New York.
5 Do you understand that?
6 MR. KUM: Objection.
7 Misstates testimony.
8 Was there a question?
9 MS. GEMAN: Yes.
10 BY MS. GEMAN:
11 Q. Do you understand that?
12 A. Well, you said contrary.
13 I said Galleri does have --
14 IDE -- I don't -- where is the -- I don't
15 say that it's CLIA certified?
16 Q. Well, that's a good
17 question. What is IDE approval?
18 A. Investigative device
19 exemption. It's just so that it can be
20 used in clinical trials.
21 Q. Do you believe that -- and
22 is it used in clinical trials?
23 A. I just mentioned the
24 PATHFINDER study. There's actually three

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1 big ones going on right now. PATHFINDER,
2 STRIVE, something else. Everyone would
3 love to know if this is effective.
4 Again, we all hate cancer.
5 Q. How many oncologists are
6 already using Galleri?
7 A. I don't know any that are
8 using it.
9 Q. How many oncologists are
10 there in the U.S.?
11 A. I don't know that.
12 Q. If I told you there is about
13 13,000, does that seem accurate?
14 MR. KUM: Don't guess.
15 THE WITNESS: I have no
16 idea.
17 BY MS. GEMAN:
18 Q. Do you know what percent of
19 those are already using Galleri?
20 A. (Shaking head.)
21 THE COURT REPORTER: You
22 have to answer.
23 THE WITNESS: No.
24 MR. KUM: Could you just

Page 178

1 verbally answer?
2 Could you re-ask the
3 question?
4 BY MS. GEMAN:
5 Q. Do you know what percent of
6 oncologists are already using Galleri?
7 A. I do not.
8 Q. Well, do you have any
9 estimate?
10 A. I have none.
11 Q. Okay. If it's more than a
12 thousand, would that surprise you?
13 MR. KUM: Calls for
14 speculation.
15 THE WITNESS: I have no
16 idea.
17 BY MS. GEMAN:
18 Q. Given that it's already
19 in -- let me ask a different question.
20 Do you have any reason to
21 believe that it won't be FDA approved as
22 soon as next year?
23 A. I have no idea.
24 Q. Have you ever -- have you

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1 heard any -- I mean, you -- sometimes
2 one -- sometimes there's information
3 pre-FDA determination that leads one to
4 have doubt as to whether a drug might be
5 approved.
6 Do you agree?
7 A. I don't know the process of
8 the FDA nor do I get that, like,
9 preapproval. But it sounds reasonable.
10 Q. For example, there might
11 be -- have you ever read about a study
12 that didn't meet one of its clinical
13 endpoints?
14 A. Of course.
15 Q. Okay. And have you ever
16 read news about a drug that -- where
17 there is consensus or belief among
18 medical professionals that FDA approval
19 is in doubt?
20 A. Broadly, I'm sure I have
21 heard that.
22 Q. Have you heard that about
23 Galleri?
24 A. I have not heard anything

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1 about. I just really focused on the
2 research aspect. And I think the key
3 here is the data to date about early
4 stage findings because that's really the
5 question here.
6 Can it be used as a
7 screening tool to find early stage
8 cancers when it's at an intervenable
9 interval.
10 There is no data, and I will
11 share with you as I did in this letter.
12 I do not know that any of the high risk
13 clinics nationally are using it, the high
14 risk clinics.
15 Q. Do you find 14 percent a low
16 number?
17 A. Yes. That means that -- and
18 again, this is in patients with confirmed
19 Stage I cancer. It means that 86 percent
20 don't think they have cancer. And that's
21 devastating if they do.
22 Q. So I want to make sure I
23 understand the statistic.
24 Your understanding is that

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1 there's an 86 percent false negative
2 rate?
3 A. Yes.
4 Q. Okay. And when people are
5 using Galleri, is that the only
6 healthcare they're getting?
7 A. I don't know.
8 Q. Did Dr. Kaplan suggest use
9 of Galleri to the exclusion of other
10 treatments?
11 A. He just said he's using it.
12 Q. Is it your understanding
13 that Dr. Kaplan suggested using Galleri
14 to displace all other care?
15 A. Can we look at his -- I
16 don't recall. Can we look at his
17 deposition?
18 Q. You can tell me your
19 recollection of that. No, we can't look
20 at his deposition.
21 MR. KUM: She can ask you
22 whatever question. You can answer
23 it.
24 THE WITNESS: I don't recall

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1 one way or another.
2 BY MS. GEMAN:
3 Q. So your primary concern
4 about Galleri, or one of them, is the
5 false negative rate in early stage
6 cancers, correct?
7 A. And, you know -- yes. I
8 mean, the good news is it didn't seem to
9 have false positives.
10 Q. Meaning people, if it said
11 you had something, you had something?
12 A. Yes.
13 Q. Okay. You mentioned before
14 a concern a patient getting a large bill.
15 Can you explain -- or an unexpected bill.
16 I'm not trying to put words in your
17 mouth. But can you tell me what you
18 meant by the link between FDA approval
19 and billing?
20 A. So I don't know the
21 insurance companies' process on paying
22 for a study that's not FDA approved or in
23 the guidelines. And we've certainly had
24 patients get bills, even for approved

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1 tests, and they are large.
2 And the other point I'd like
3 to make is that there are tests that are
4 FDA approved that we don't yet use in our
5 cancer practice. So FDA approval in and
6 of itself is not the only metric,
7 although I find it important.
8 For example, there's a test
9 called -- and it goes again to ordering a
10 study and then not knowing what to do
11 with the results, which is the harm.
12 There is a test that is FDA
13 approved -- we're actually not sure how
14 in the oncology world -- called
15 Signatera. And it assesses the presence
16 or absence of circulating tumor material
17 for colon cancer.
18 And the way that it's
19 indicated is after the cancer is removed
20 and before you start chemo, if there are
21 cancer cells in the bloodstream detected,
22 the risk of recurrence is higher. That's
23 what it tests. And if at the end, they
24 draw this test and it clears, your risk

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1 of recurrence is lower.
2 The problem is, it doesn't
3 say, if you draw this test it is
4 positive, and you draw it after the six
5 months are chemo are done and it's
6 positive, what do you do? You have no
7 measurable disease in the body. You have
8 no tumor marker. You don't know what
9 you're treating.
10 Do you watch this anxious
11 patient who knows they have circulating
12 tumor colon cancer cells? Do you try a
13 different chemo?
14 And even though it's FDA
15 approved, it's not really clear what to
16 do with the test.
17 So in our practice, we only
18 use it within a context of a clinical
19 trial because, again, it causes anxiety
20 without meaningful intervention.
21 So FDA approval is one
22 metric. It's not the only. And it would
23 have to have the indication of early
24 screening in an asymptomatic patient as

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1 one of the indications, and it would have
2 to be vetted by the United States
3 Preventive Task Force because it's in the
4 arena of cancer screening in asymptomatic
5 patients.
6 Q. What was the name of that
7 test?
8 A. Signatera.
9 Q. Where in Dr. Kaplan's report
10 did you see his recommending it?
11 A. He didn't.
12 Q. He didn't. Okay.
13 A. I'm explaining to you the
14 risk of ordering tests and then not
15 knowing what to do with them. Another
16 good one in there --
17 Q. Well, hang on.
18 MR. KUM: Hang on.
19 BY MS. GEMAN:
20 Q. There's no question.
21 There's no question.
22 A. Sorry.
23 Q. Wait for the question.
24 Are there other clinical

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1 facilities that use Signatera, yes or no?
2 A. I assume yes.
3 Q. Okay. So there's a dispute
4 of opinion about that particular test and
5 its efficacy?
6 A. In -- I don't know about --
7 I mean, it's accurate at measuring the
8 cancer cells. The question is then what
9 do you do with it.
10 Q. There's a dispute of opinion
11 among oncologists as to whether to use
12 that particular test, Signatera, correct?
13 A. I don't know that it's a
14 dispute. I think the question is, what
15 do you do with the results.
16 Every time you order a test,
17 you have to think about the results
18 because that's where the potential for
19 harm comes. It's easy --
20 Q. Some oncologists -- some
21 oncologists use the test; some do not,
22 correct?
23 A. I presume, yes.
24 Q. Similarly with Galleri, some

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1 oncologists use it, some do not, correct?
2 A. That's what I heard from
3 you.
4 Q. Do you have any independent
5 knowledge otherwise?
6 A. I don't know anyone that's
7 ordered it.
8 Q. Do you dispute that there
9 are hundreds, maybe even more than a
10 thousand, providers that have used it?
11 MR. KUM: Objection. Calls
12 for speculation.
13 Don't guess.
14 THE WITNESS: I have no
15 idea.
16 BY MS. GEMAN:
17 Q. Have you discussed Galleri
18 with colleagues outside of this
19 litigation?
20 A. Only thing I asked is if we
21 are using it in the high risk setting.
22 If we have it on -- I mean, there was
23 nobody ordering it.
24 Q. And was -- is some of the

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1 concern, not all, but some of the concern
2 about its use, the price tag?
3 A. That actually wasn't the
4 concern. The concern is that it's not a
5 validated screening tool. And it has
6 poor results in early screening, Stage I
7 and Stage II.
8 Q. When you mentioned earlier
9 the concern about the test, that if it's
10 not FDA approved, the consumer might have
11 to pay, are you now withdrawing that
12 testimony?
13 MR. KUM: Objection. Vague
14 and ambiguous.
15 THE WITNESS: I don't really
16 understand your question. I think
17 they're kind of unconnected. But
18 I'm happy to hear it again.
19 BY MS. GEMAN:
20 Q. Sure. You testified a bit
21 ago that one concern for you with not
22 using an FDA-approved intervention is
23 that it might not be covered by
24 insurance; is that correct? Do you

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1 recall that testimony?
2 A. It was the opposite. I said
3 if it's not FDA approved, I would be
4 concerned that the patient would carry
5 the economic toxicity.
6 Q. I'm sorry. I said it
7 converse. But that's what I meant.
8 So one concern with using a
9 drug that is not FDA approved is the
10 financial impact on the patient?
11 A. You know, patients have
12 tremendous economic toxicity from all of
13 the tests. We write a prescription or
14 order a test. We don't always know and
15 they don't always tell us when the bill
16 comes.
17 I do have patients bring the
18 bill to me. And it's incredibly
19 stressful. And we help them work through
20 it, and we contest it, often for things
21 that are approved.
22 So even without the
23 conundrum of ordering a non-FDA-approved
24 or a test that's not indicated in that

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1 setting, we have patients getting bills,
2 and I've had patients be foreclosed upon
3 for tests that are certainly covered.
4 And so for me, with this
5 vulnerable class of patients, I have to
6 be sure they are not going to get a bill.
7 I will say that the task
8 force guidelines were created without
9 regard to the cost of the testing.
10 So it was completely
11 financially blind when they were
12 assessing the screening tests.
13 Q. And how much, in your
14 experience, of patient anxiety about
15 testing relates to -- great phrase that I
16 hadn't used before -- economic toxicity?
17 A. So this is actually just
18 that and "scanxiety." These are terms
19 that are just -- it's sort of a brand-new
20 field of study.
21 And you have to imagine, if
22 you're ill and you have a limited time to
23 live, we're actually studying the burden
24 of waiting room time, travel time. This

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1 is sort of a whole new field looking
2 at -- in health sciences research
3 actually, to look at all of the impacts
4 of our cancer care on our patients, not
5 just the side effects of the chemotherapy
6 or the symptoms from the cancer.
7 Q. And so thank you. I
8 appreciate that clarification.
9 How much of patient anxiety
10 in testing relates to economic toxicity,
11 in your view?
12 A. They all ask me, "Am I going
13 to get a bill?" I had a patient -- I
14 have a patient on a Signatera trial we're
15 getting -- we're doing. And she said --
16 she messaged into our office and called
17 two times and said, "Am I going to get
18 billed for this?" Patients are very
19 anxious. Our supportive -- yeah.
20 Q. Were you done with your
21 answer?
22 A. Yes, relating to that.
23 Q. And you -- I'm going to give
24 you a hypothetical.

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1 Let's say a 73-year-old was
2 exposed to substances that are proven to
3 raise his risk of prostate cancer by a
4 statistically significant degree.
5 And he is otherwise very
6 healthy.
7 Do you think it's
8 appropriate to screen him for prostate
9 cancer?
10 MR. KUM: Incomplete
11 hypothetical.
12 You can answer if you can.
13 THE WITNESS: I do not.
14 BY MS. GEMAN:
15 Q. What about for lung cancer?
16 A. I'm going to go back to the
17 prostate cancer, if I may.
18 Q. Well, no, no, if I may, I
19 meant specifically a 73-year-old was
20 exposed to substances that are proven to
21 raise his risk of lung cancer by a
22 statistically significant degree, and
23 he's otherwise healthy.
24 Would you consider it

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1 appropriate to screen him for lung
2 cancer?
3 MR. KUM: Incomplete
4 hypothetical.
5 You can answer if you can.
6 THE WITNESS: I would not.
7 BY MS. GEMAN:
8 Q. You would not.
9 What would need to change
10 about the hypothetical to incline you to
11 recommend screening for lung cancer for
12 that gentleman?
13 MR. KUM: Assumes facts not
14 in evidence. Calls for
15 speculation.
16 THE WITNESS: Again,
17 exposures don't change guidelines,
18 generally, in asymptomatic
19 patients.
20 I'll just say, you know, it
21 takes decades for people to make
22 cancer. That's been well
23 established.
24 I don't know what the life

<p style="text-align: right;">Page 194</p> <p>1 expectancy of a 73-year old is. I 2 don't know if that fits in with 3 the magnitude of risk and 4 magnitude of benefit. 5 I personally would not 6 screen that person for lung 7 cancer. 8 BY MS. GEMAN: 9 Q. So if that person came in 10 your office and said essentially -- 11 incredibly healthy guy. Let's say he has 12 a living parent even. His mom is living. 13 And you learned that he was, 14 in the workplace, exposed to a substance 15 that gave him a dramatically higher risk 16 of lung cancer, and he wanted to be 17 screened. You would tell him what? 18 MR. KUM: Incomplete 19 hypothetical. 20 THE WITNESS: You know, is 21 the risk of being exposed to 22 ionizing radiation without a -- 23 you know, referring -- exposure 24 that hasn't changed the</p>	<p style="text-align: right;">Page 196</p> <p>1 wouldn't go to an oncologist because they 2 would have to go through an internist 3 first, basically? 4 A. Oh, we don't see patients 5 without a biopsy. 6 Q. Do you understand that there 7 are oncologists who see patients who just 8 want to make an appointment because of 9 their concerns or what have you? 10 MR. KUM: Calls for 11 speculation. 12 THE WITNESS: In private 13 practice, probably, not at an 14 academic center. 15 BY MS. GEMAN: 16 Q. But you don't dispute, then, 17 in private practice, doctors see patients 18 without a biopsy frequently, correct? 19 A. I've never even thought 20 about that. It's not really something I 21 think about. Most every -- there's the 22 mnemonic, "Tissue is the issue. Cancer 23 is the answer." 24 It sounds funny. But</p>
<p style="text-align: right;">Page 195</p> <p>1 guidelines, I wouldn't do it. I 2 wouldn't test him. 3 BY MS. GEMAN: 4 Q. Do you think most 5 oncologists would or would not test that 6 person? 7 A. Again, this is going to be 8 not an oncologist. This will be in the 9 internal medicine space. 10 He would not be coming to an 11 oncologist for some report of an 12 exposure. 13 I don't even know if that 14 test would be covered under that 15 indication. I suspect not. I do not 16 think someone would order it for that 17 indication. 18 Q. Let's assume the test was 19 paid for by the employer who caused the 20 exposure, and so he doesn't have to pay 21 for it. 22 Do you think most -- and 23 sorry, let me go back. If somebody was 24 afraid of lung cancer, you think they</p>	<p style="text-align: right;">Page 197</p> <p>1 everything we do is based on pathology. 2 I assume what you're saying 3 is they are seeing them in their -- their 4 internal medicine Hatt. I don't 5 understand why that would happen. But it 6 sounds like you know that it does. 7 Q. Just -- you've been an 8 oncologist for decades, right? 9 A. Mm-hmm. 10 MR. KUM: You have to give a 11 verbal answer, Doctor. 12 THE WITNESS: I've been an 13 oncologist, yes, two decades. 14 BY MS. GEMAN: 15 Q. Do you feel you have an 16 understanding of the sort of range of 17 conditions or presenting conditions or 18 reasons why patients go see private 19 oncologists? 20 MR. KUM: Objection. Vague 21 and ambiguous. 22 BY MS. GEMAN: 23 Q. Do you know why people see 24 oncologists?</p>

<p style="text-align: right;">Page 198</p> <p>1 A. When they're diagnosed with 2 cancer. 3 Q. Okay. Do you know why, 4 outside of that, people see oncologists? 5 A. I don't know why. 6 Q. Okay. You're not aware of 7 people who are just concerned because of 8 an exposure seeing -- making an 9 appointment to see an oncologist? 10 A. I just know that I wouldn't 11 see that patient without a confirmed 12 cancer. 13 Q. But are you aware -- do you 14 have any knowledge at all about the 15 extent to which private practice 16 oncologists might see that patient, or 17 for that matter, oncologists in other -- 18 in other hospital settings? 19 MR. KUM: Calls for 20 speculation. 21 THE WITNESS: I have no 22 idea. 23 BY MS. GEMAN: 24 Q. Let us, in we could, turn</p>	<p style="text-align: right;">Page 200</p> <p>1 three, four, five -- 6, at last year's 2 ASCO. 3 The problem is that Covid 4 has really slowed down data acquisition, 5 not just for these trials, but for a lot 6 of studies, so there hasn't been much 7 lately that I could find. And so that's 8 why I commented on that being the most 9 extensive data to date. 10 Q. And why is it -- in your 11 view, is it good if a test does not have 12 false positives? 13 A. If a test does not have 14 false -- is it good? 15 Q. Mm-hmm? 16 A. False positive. I don't 17 know that I said it's good. 18 Q. Sorry. I'm asking. In your 19 view, is it good if a test does not have 20 false positives? 21 A. Yes, because otherwise 22 you're subjecting a patient to a 23 potentially risky and invasive workup. 24 And the more you test them, the more</p>
<p style="text-align: right;">Page 199</p> <p>1 to -- well, I apologize. Before we leave 2 Page 20 and 21 about Galleri, other than 3 the company's own website and the 4 articles cited in Footnotes 44 and 45, 5 are you relying on any materials about 6 Galleri? 7 A. I think I mentioned the 8 abstract I looked at in ASCO. It's 9 actually very hard to find out much about 10 Galleri because the studies are in 11 process, which is not unusual. 12 So, you know, I've really 13 tried hard to find information. 14 Q. Can you tell me -- I 15 don't -- forgive me. I don't recall the 16 abstract that you mentioned in ASCO. 17 Can you tell me if that's 18 cited in the report here? 19 A. I just mentioned that a 20 poster, which again, is not -- is 21 usually -- an abstract is presented on a 22 poster of any updated data, was presented 23 by the -- by Thomas Bayer. 24 So in Number -- one, two,</p>	<p style="text-align: right;">Page 201</p> <p>1 likely you'll have false positives. So 2 yeah, that can be devastating for a 3 patient. 4 Q. If a test does not have 5 false positives, then having that test 6 frequently does not engender a risk of 7 false positives, correct? 8 A. So there's no test that does 9 not have false positives. 10 The whole premise is, you 11 know, we learn a lot about -- and you 12 probably came across this -- sensitivity 13 and specificity. And these are the way 14 we grade the value of a test or a study. 15 Sensitivity means true 16 positive. You really want the positive 17 patients to really have whatever you're 18 looking for. 19 And the other really 20 important thing is specificity, which is 21 true negative. You don't want to get a 22 negative result and in fact the patient 23 has cancer. 24 That was my point on the</p>

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1 Stage I, Stage II findings of Galleri,
2 that you will have 60 to 86 percent of
3 the patients potentially feeling
4 reassured that they don't have cancer
5 when they do.
6 Q. If a test is highly
7 sensitive, recurrent use of that test
8 doesn't change its sensitivity; isn't
9 that correct?
10 A. I believe the sensitivity is
11 set out, but there is no test that
12 doesn't have false positive or false
13 negatives.
14 Those specificity rates are
15 the -- the best ones are always in the
16 90 percent. But none of them are ever
17 100 percent.
18 Q. When you say the specificity
19 rates are in the 90 percent --
20 A. A good test.
21 Q. Sorry.
22 -- do you mean the
23 sensitivity rates or --
24 A. Both. You grade them with

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1 both, sensitivity and specificity.
2 Q. But again, if a test, is
3 highly -- strike that.
4 When you say that, quote,
5 the sensitivity is set out, you mean that
6 a highly sensitive test doesn't become
7 less highly sensitive on repeat use,
8 correct?
9 A. It should have the same
10 statistic. But it's never 100 percent.
11 Q. Can we please turn to Page 4
12 of your report.
13 A. Yes.
14 Q. I'm looking at the
15 third-to-last sentence where you say,
16 "Screening for and surveillance of
17 Barrett's esophagus is a controversial
18 topic among gastroenterology societies,
19 and no guidelines exist in USPSTF
20 recommendations for serial endoscopy."
21 Do you see that?
22 A. Yes.
23 Q. What is the cite for the
24 proposition that screening and

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1 surveillance of Barrett's esophagus is
2 controversial?
3 A. I don't remember which one
4 of these articles that specifically came
5 from. Let me just look at nine, because
6 sometimes if I cite it, I carry on after.
7 I would guess that it was --
8 Q. It's right after Footnote
9 11.
10 MR. KUM: Doctor, you have
11 your references there, if you want
12 to just pull them.
13 THE WITNESS: Oh, yeah.
14 MR. KUM: But take off your
15 microphone first.
16 THE WITNESS: So, yeah. No,
17 I mean, in my -- the way that I
18 write things out, and again, I
19 would have to -- I'm happy to look
20 at the article and find it. But
21 the way I usually cite things, it
22 would be from that 11 on down.
23 BY MS. GEMAN:
24 Q. Okay. So if we wanted to

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1 look for an article that stated that
2 proposition, we should look to the JAMA
3 article in Footnote 11, or perhaps the
4 article in Discovery Med on footnote 12?
5 A. I'm happy to look through
6 them.
7 Q. No, I'm sorry, Footnote 12
8 is Gastric.
9 And do you recall reading an
10 article that said that screening for and
11 surveillance of Barrett's esophagus is
12 controversial? Or is that your
13 inference?
14 A. Well, I know it's
15 controversial because most centers don't
16 do it.
17 But I'm not sure.
18 Q. What do you mean by
19 controversial?
20 A. So a lot of this is in the,
21 you know, American Gastric Society.
22 There's differences between the Europeans
23 and the Americans. Sometimes -- some say
24 you should never scope again serially.

<p style="text-align: right;">Page 206</p> <p>1 Some day one scope, and that's the 2 standard. I think they used to say 3 scopes every two years and then went out 4 of favor. 5 So some of this is just what 6 I've learned over the years. And so it 7 may not be specifically cited. It may go 8 to my clinical knowledge and experience. 9 Q. Okay. And if you could 10 please turn to Page 9. Do you see that 11 between Pages 9 and 13, there's -- 12 there's a number of charts imported? 13 A. Yes. 14 Q. And those were taken 15 verbatim from the task force website? 16 A. Correct. 17 Q. Okay. So you did not change 18 the language in these charts, correct? 19 A. I couldn't even correct 20 anything of them, if it got cut off. I 21 don't know why. 22 Q. Okay. Is there a reason 23 that you didn't use the updated C 24 definition?</p>	<p style="text-align: right;">Page 208</p> <p>1 practice in what you cited is, "Offer or 2 provide this service only if other 3 considerations support the offering or 4 providing this service in an individual 5 patient." 6 Do you see that? 7 A. Mm-hmm. 8 Q. If I tell you that the 9 current language is, "Offer or provide 10 this service for selected patients 11 depending on individual circumstances" -- 12 well, first of all, does that sound 13 familiar? 14 A. I don't know that I've read 15 that. 16 Q. Okay. Does that seem more 17 sort of pro-screening or less or neither? 18 A. I think, to me, that would 19 read, you know, if a patient had medical 20 comorbidities that would make it, you 21 know, tough for the patient or without an 22 opportunity to -- circumstances, to me, 23 says what the patient's circumstances 24 are. It would probably be their health</p>
<p style="text-align: right;">Page 207</p> <p>1 A. I'm not sure what that is. 2 Q. So if you see Grade C on 3 Page 9. 4 A. Yes. 5 Q. Okay. And you note that 6 that statement was undergoing revision? 7 A. You know, at whatever point 8 I pulled it, that's what it said. So I 9 can look. I think it was when I pulled 10 it January 2022. And I know because this 11 came up when we were printing off all of 12 the articles and stuff for the binders. 13 And the comment was, that's what I cited. 14 So I don't know if it had changed in the 15 interim. 16 I guess that's your 17 question. There wasn't a reason. 18 Q. Okay. Do you know if the 19 current definition for C is more 20 pro-screening or less pro-screening? 21 A. I don't know. This is what 22 it was when I looked at it. I'd love to 23 know. 24 Q. Well, the suggestion for</p>	<p style="text-align: right;">Page 209</p> <p>1 circumstance. 2 I think we're -- you know, 3 I'm not sure what the benefit is of fine 4 tuning this recommendation. But 5 circumstance to me would speak to the 6 patient's circumstance, their health and 7 well-being. 8 And perhaps, you know, if a 9 patient is sick you wouldn't want to put 10 them through a test. 11 Q. And is it your understanding 12 that the new definition of C was slightly 13 less focused on patient preferences and 14 more on professional judgment? 15 A. I'm not sure. I don't know 16 the answer to that. 17 Q. Then I want to talk about 18 something that you said on Page 11, 19 please. 20 Now, it's your interest in 21 limiting risk of harm from, quote, 22 unnecessary or unreliable 23 tests/procedures? 24 A. Yeah.</p>

<p style="text-align: right;">Page 210</p> <p>1 Q. Correct?</p> <p>2 A. Correct.</p> <p>3 Q. What is your -- what is the</p> <p>4 distinction between unnecessary and</p> <p>5 unreliable?</p> <p>6 A. Oh. That's straightforward.</p> <p>7 So for example, the task</p> <p>8 force does not -- the task force does not</p> <p>9 recommend checking a PSA. It has a D</p> <p>10 level of recommendation.</p> <p>11 It used to be a stronger</p> <p>12 recommendation, but they discovered over</p> <p>13 time that even though they were</p> <p>14 diagnosing cancers earlier, it didn't</p> <p>15 change the overall survival.</p> <p>16 I actually was speaking</p> <p>17 to -- when I was writing this, I was</p> <p>18 really thinking about Dr. Kaplan's</p> <p>19 recommendation for sending inflammatory</p> <p>20 markers.</p> <p>21 Inflammatory markers are</p> <p>22 erythrocyte sedimentation rate or CRP.</p> <p>23 Because these can be elevated in a lot of</p> <p>24 conditions including vascular disease,</p>	<p style="text-align: right;">Page 212</p> <p>1 of when a test becomes unreliable. Do</p> <p>2 you have a threshold for specificity and</p> <p>3 sensitivity?</p> <p>4 A. I mean, in this case I would</p> <p>5 follow the tests put forth by the task</p> <p>6 force.</p> <p>7 Q. Well, I'm asking a different</p> <p>8 question, which is what is -- in your</p> <p>9 view the threshold for sensitivity and</p> <p>10 specificity to warrant a test being</p> <p>11 considered reliable?</p> <p>12 A. I haven't evaluated all the</p> <p>13 tests in terms of that. That was not</p> <p>14 what was asked of me in going for the</p> <p>15 this mission.</p> <p>16 I'm happy to go through all</p> <p>17 of his recommended medical monitoring.</p> <p>18 And I'm happy to give an opinion on that.</p> <p>19 Q. Do you have an opinion about</p> <p>20 the threshold for sensitivity and</p> <p>21 specificity that must be reached for a</p> <p>22 test, in your view, to be considered</p> <p>23 reliable?</p> <p>24 A. I don't know a number there.</p>
<p style="text-align: right;">Page 211</p> <p>1 and I don't know what one would do with</p> <p>2 the information of an elevated</p> <p>3 inflammatory marker. It does not</p> <p>4 necessarily mean cancer or infection.</p> <p>5 In fact, I do believe that I</p> <p>6 listed a long list of things that it</p> <p>7 could be.</p> <p>8 So that, to me, is a test</p> <p>9 that is unreliable.</p> <p>10 Q. What is the distinction</p> <p>11 you're drawing between unnecessary and</p> <p>12 unreliable?</p> <p>13 A. You know, I think</p> <p>14 unnecessary, like a task force</p> <p>15 recommendation, you know, it's important</p> <p>16 what they recommend and what they do not</p> <p>17 recommend. So that would be in the</p> <p>18 unnecessary category.</p> <p>19 Whereas, a test that may</p> <p>20 falsely elevate a patient's fear of</p> <p>21 cancer, if it's being tested in a cancer</p> <p>22 screening and is not a sensitive or</p> <p>23 specific test, that would be unreliable.</p> <p>24 Q. And what's your definition</p>	<p style="text-align: right;">Page 213</p> <p>1 I mean, you always want as high as you</p> <p>2 can for both numbers. I'm going to leave</p> <p>3 it there.</p> <p>4 Q. And a lot of tests are high</p> <p>5 on one number and low on the other,</p> <p>6 right?</p> <p>7 A. The best tests are higher on</p> <p>8 both.</p> <p>9 Q. But a lot of tests are high</p> <p>10 on one number and low on another,</p> <p>11 correct?</p> <p>12 A. I'm not sure.</p> <p>13 Q. Are you -- I mean, you use a</p> <p>14 lot of tests in your -- in your work; is</p> <p>15 that right?</p> <p>16 A. Well, I mean, what do I</p> <p>17 order? I order a CBC. I order a liver</p> <p>18 panel, a kidney panel. And I order tumor</p> <p>19 markers. That's the general testing that</p> <p>20 I order for a cancer patient when I'm</p> <p>21 supervising their chemotherapy.</p> <p>22 Q. So to the extent that</p> <p>23 Dr. Kaplan suggests similar tests, then</p> <p>24 you would agree that those are necessary</p>

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1 and reliable?

2 A. I think you have to know

3 what the context is. He is recommending

4 in the setting of screening asymptomatic

5 patients. I'm using them in the setting

6 of giving these patients cytotoxic

7 chemotherapy and monitoring their safety

8 and response.

9 Q. Are there -- and you

10 understand that Dr. Kaplan is

11 recommending screening in the context of

12 patients who were exposed to carcinogens

13 that, in his framework, are causally

14 linked with certain specific cancers,

15 correct?

16 MR. KUM: Objection.

17 Assumes facts not in evidence.

18 THE WITNESS: He said he

19 based his assumptions and sort of

20 was very careful about that, of

21 reading three expert letters from

22 the plaintiffs.

23 He sort of -- I don't even

24 understand how he picked some of

Page 215

1 these tests -- puts together a

2 potpourri of screening tests

3 without any evidence offered and

4 without any thought to whether or

5 not they're safe or appropriate

6 for these patients: It's honestly

7 a strange collection.

8 And I -- it doesn't pass the

9 sniff test for me. I would not

10 subject myself or my loved one to

11 those tests.

12 BY MS. GEMAN:

13 Q. He's seen tens of thousands

14 and treated tens of thousands of cancer

15 patients and is a well regarded

16 physician.

17 Do you believe that his

18 protocol was entered into without regard

19 for the safety of patients?

20 MR. KUM: Objection.

21 Assumes facts not in evidence.

22 Go ahead.

23 THE WITNESS: He is a lovely

24 private practice physician who

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1 maintains an academic affiliation

2 so that he can do teaching, which

3 I find very lovely, mentoring of

4 oncology fellows in his clinic.

5 I cannot -- he doesn't

6 really explain his thought process

7 or give any evidence or

8 explanation for his test

9 recommendations.

10 So I can't -- I've been

11 trying to understand his thought

12 process. I have -- I can't.

13 It is not evidence or data

14 driven.

15 BY MS. GEMAN:

16 Q. In your opinion?

17 A. That's what you were asking,

18 right?

19 Q. Yes.

20 A. Okay. In my opinion, there

21 is no merit to this testing protocol.

22 Q. So to the extent that he's

23 suggesting tests that are within the

24 standard of care, do you think they've

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1 become rendered meritless by his dint of

2 suggesting them?

3 MR. KUM: Objection.

4 Assumes facts not in evidence.

5 THE WITNESS: I actually

6 went through his list and I

7 assessed sort of what standard of

8 care.

9 I looked at -- you know, I

10 was sort of surprised to hear that

11 a CBC is -- you don't have to

12 order that every year in a primary

13 care visit.

14 A liver and kidney panel,

15 you actually don't have to.

16 The only mandated things are

17 the history and physical.

18 The primary care would also

19 recommend against thyroid testing.

20 There's no mention of inflammatory

21 markers.

22 You know, it's -- I can go

23 through that list with you. I'd

24 be delighted, because I actually

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1 put that exact question to the
2 test reviewing each of his
3 proposed medical monitoring study.
4 BY MS. GEMAN:
5 Q. Do you agree that patients
6 should have -- and specifically patients
7 who have been exposed to a carcinogen
8 that is causally linked in this scenario
9 to various cancers, including many that
10 even you agree can be, you know, treated
11 if caught early -- annual physicals?
12 A. Annual physical is standard
13 primary care. It's already done.
14 Q. And do you think it's
15 appropriate to have questions directed
16 towards signs/symptoms of malignancies?
17 A. That's actually done at
18 every primary care visit also.
19 You know, the -- what we're
20 taught, the art of medicine, actually
21 it's talking to the patient and examining
22 the patient. You get a lot of
23 information.
24 And to your point with

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1 asking questions or directing to
2 exposure, the history -- the history is
3 sort of the age old fundamental of the
4 primary care visit, and specifically a
5 yearly visit.
6 MR. KUM: Counsel, whenever
7 you get to a reasonable breaking
8 point, can we take a break?
9 MS. GEMAN: We can do that
10 now.
11 THE WITNESS: I'd love that.
12 Thank you.
13 THE VIDEOGRAPHER: All
14 right. 2:04. We are off the
15 video record.
16 (Short break.)
17 THE VIDEOGRAPHER: 2:16. We
18 are on the video record.
19 BY MS. GEMAN:
20 Q. Doctor, would you please
21 turn to Page 14 of your report.
22 Do you see you have a
23 section on patient anxiety/psychological
24 distress?

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1 A. Yes.
2 Q. And among other things you
3 state that, "Patients in established
4 higher risk categories with validated
5 enhanced screening protocols are known to
6 have more psychological distress
7 associated with screening, even if
8 ultimately found to be at average risk.
9 False positives also generate a lot of
10 anxiety at the time of the positive test
11 result and with subsequent screening
12 tests."
13 A. Yes.
14 Q. Okay. Just to help me, what
15 is the cite for that?
16 A. So, again, 36 going down.
17 Q. That's Chad-Freidman?
18 A. And actually 37. I don't
19 know why I changed my format, because 37,
20 "Implications of False Positives," should
21 actually be at the end of -- because
22 that's where it really starts --
23 "Screening Findings and Workups."
24 MS. GEMAN: All right. So

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1 let's, if we could, mark as
2 Exhibit 5 the article cited in
3 Footnote 36 of the doctor's report
4 which is "Psychological Distress
5 Associated With Cancer Screening.
6 A Systematic Review."
7 (Document marked for
8 identification as Exhibit
9 Teitelbaum-5.)
10 THE WITNESS: Is this the
11 same thing?
12 BY MS. GEMAN:
13 Q. What's been marked as
14 Exhibit 5 is an article in the journal
15 Cancer; is that correct?
16 A. Yes.
17 Q. And that is a well regarded
18 peer-reviewed journal?
19 A. Yes.
20 Q. Okay. And if you could --
21 well, let me ask first, do you know any
22 of the authors of this study?
23 A. I do.
24 Q. Do you know them -- do you

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1 work with them or do you know them
2 personally?
3 A. It looks like they're
4 psychiatrists, so no. And in Boston, so
5 no.
6 Q. Wait, I'm sorry. You do
7 know them personally or you do not?
8 A. I do not know them at all.
9 They are in Boston, and they are
10 psychiatrists.
11 Q. Okay. I misunderstood or
12 misheard your earlier answer. And if you
13 could turn to Page 3892, which is the
14 last substantive page of the article.
15 And can you please read the
16 first sentence of the conclusions?
17 A. Under summary of results or
18 under discussion?
19 Q. Under conclusions.
20 A. Which page?
21 Q. Page 3892. Or I can read
22 it. That's fine. Just look on, please,
23 Page 3892.
24 A. Yes.

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1 Q. Do you see the first
2 sentence reads, "For this review, we
3 examined the literature on distress at
4 cancer screening and concluded that, with
5 the exception of colorectal cancer
6 screening, distress associated with
7 cancer screening itself is low."
8 Do you believe they made the
9 proper inferences from their data?
10 A. I mean, I would have to -- I
11 would ask then to have some time to go
12 through the article.
13 I think the question is, if
14 this is in the setting of asymptomatic
15 general screening or -- I think the point
16 I was showing was if Dr. Kaplan is
17 calling this population high risk, that
18 there's a different anxiety level
19 associated with the recommended
20 screening.
21 Q. Well, are you changing your
22 opinion on what this article purportedly
23 concludes or supports?
24 MR. KUM: Objection.

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1 Argumentative. Misstates
2 testimony.
3 THE WITNESS: I'd have to
4 read through the article again.
5 I'm happy to do that now.
6 MR. KUM: Doctor, take your
7 time.
8 THE WITNESS: Yeah.
9 MR. KUM: Go ahead.
10 BY MS. GEMAN:
11 Q. Did you -- well, I'm not
12 asking you to read the whole article.
13 MR. KUM: Well, but
14 Counselor, you've just given her
15 an article to read, which is a
16 paper which is numerous pages
17 long. She wasn't -- she's not
18 required to memorize this from --
19 you know, word for word.
20 And she's just asked if she
21 could just be given a minute to
22 review it. So if you're not
23 allowing her to review it, okay, I
24 want that on the record. But

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1 she's just asked if she could just
2 have a minute to simply flip
3 through it.
4 MS. GEMAN: Well, let me ask
5 my question.
6 BY MS. GEMAN:
7 Q. And absolutely if you need
8 to review it to answer the question, of
9 course that's completely fine. Take all
10 the time you need.
11 Did you read the article
12 before citing it in your report?
13 A. Yes.
14 Q. Okay. And for what
15 proposition were you citing this article?
16 A. So just speaking to the
17 sentence that was written, you know, it's
18 a little bit out of context, which is why
19 I think it would be useful for me to have
20 some time with the article.
21 Let me just look at my
22 paragraph again.
23 Q. Sure.
24 A. And again, I say here, the

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1 bulk is -- of anxiety associated with a
2 more invasive procedure, screening,
3 colonoscopy.
4 I have to look back -- it's,
5 you know, been about two months --
6 whether or not this differentiates
7 between average risk and high risk.
8 I suspect this is average
9 risk patients having anxiety with a
10 colonoscopy, and I have to go back again.
11 But I am concerned about the anxiety in
12 patients that have been called high risk.
13 Q. Do you know to what the
14 authors attribute the exception, meaning
15 why is it in the authors' view that it's
16 colorectal cancer screening patients who
17 had -- everyone else had low distress and
18 they had higher distress?
19 A. I don't know the answer. I
20 would have to have 20 or 30 minutes to go
21 through the article. And it just -- you
22 know, I read every line to try and
23 understand what your question is.
24 Q. And did you look for all the

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1 articles that you could find on
2 psychological distress associated with
3 cancer screening?
4 A. There are not many articles
5 that come up.
6 Q. Did you review all the ones
7 that you could find?
8 A. Yes.
9 Q. So in addition to what's
10 been marked as Exhibit 5, did you tell me
11 a minute ago that another article from
12 Cancer that you cited is "Implications Of
13 False Positive Results For Future Cancer
14 Screenings"?
15 A. Yes.
16 Q. Okay.
17 MS. GEMAN: Okay. So let's
18 please mark as Exhibit 6 the
19 article that is cited in Footnote
20 37 of the doctor's report. And
21 it's entitled "Implications Of
22 False Positive Results For Future
23 Scanning" -- I'm sorry -- "For
24 Future Cancer Screenings."

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1 (Document marked for
2 identification as Exhibit
3 Teitelbaum-6.)
4 THE WITNESS: So I'm going
5 to read these two articles now?
6 MR. KUM: Well, read the
7 next article. She moved on
8 questions from the prior article.
9 THE WITNESS: Okay.
10 BY MS. GEMAN:
11 Q. I have a general question
12 before this.
13 What is the -- does a false
14 positive mean someone is told, "You have
15 cancer," or does it mean that they're
16 told something like, "We have a result
17 that we want to follow up more on"?
18 A. I mean, a patient is told
19 they have patient. And then they get the
20 next test in the workup, and they don't
21 have cancer.
22 Q. So your testimony is when
23 there's an anomalous result, the patient
24 is told that they have cancer?

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1 A. No. They are told there is
2 a positive result, and there needs to be
3 a further workup.
4 Q. Okay.
5 A. It prompts a workup for
6 cancer.
7 Q. But not the --
8 A. That's what the anxiety is
9 associated with.
10 Q. And the concern -- or by
11 including Taksler, is one of the points
12 that you're making then a concern of a
13 false positive is that it's inherently
14 stressful and also that it might deter
15 your willingness to get more tests?
16 A. Let me just have some time
17 to read. And again, the one thing that
18 I'm going to say is the more frequently
19 you test somebody, the more chance of a
20 false positive.
21 But if I could have some
22 time with this article, I would
23 appreciate it so that I have a basis for
24 properly answering your questions.

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1 Q. Yes. Would you mind
2 answering my question first, and then you
3 can look at the article. Because my
4 question was about your report.
5 A. Oh. You were asking --
6 okay.
7 Q. Are you making the point in
8 your report that a concern of a false
9 positive, in addition to its being
10 inherently stressful, is that it might
11 deter willingness to get subsequent
12 tests? If I could just ask you that
13 question.
14 A. I'm just going to read my
15 report, if you don't mind.
16 MR. KUM: She's looking at
17 her report.
18 BY MS. GEMAN:
19 Q. Right. Well, no I was --
20 right. At your report. That's fine.
21 A. Yep.
22 Q. Go ahead.
23 A. And again, these are average
24 risk patients from cancer screening.

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1 So you're still on false
2 positive, right?
3 Q. Yeah.
4 A. What is your question?
5 Q. So what is the concern with
6 a false positive? You mentioned anxiety.
7 A. Well, there's both a
8 physical concern and a psychological
9 concern. You know, if you are then --
10 all right.
11 So let's say you have a
12 positive finding on a low dose spiral CT.
13 Well, the only way to
14 confirm or deny that you have cancer,
15 again, in our oncology world is to get a
16 biopsy.
17 A biopsy for a lung mass is
18 actually very difficult. You either have
19 to stick a needle through the chest wall,
20 and sometimes the first biopsy is not
21 conclusive and you have to do it again.
22 Or you have to do even a
23 more invasive test, where you put a scope
24 down, which, again, requires sedation and

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1 for a cardiac patient, would require
2 cardiac clearance.
3 And this is a more risky
4 test than an upper endoscopy, because it
5 requires -- goes in the airway. And then
6 when they're in the airway, they take a
7 needle and poke through the bronchus to
8 get to the lung mass to biopsy it.
9 So the only way to prove
10 cancer is a biopsy. And both of those
11 are invasive and have established risks.
12 There's no tumor marker for
13 lung cancer.
14 MR. KUM: Doctor, now you
15 can read the article.
16 MS. GEMAN: We can go off
17 the record if you want to read
18 your article.
19 THE WITNESS: Can you tell
20 me what your question is again?
21 MR. KUM: Why don't you read
22 the paper first.
23 THE WITNESS: This -- and
24 you want Number 6.

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1 MR. KUM: It's this Taksler.
2 THE VIDEOGRAPHER: Off the
3 record?
4 MS. GEMAN: Yeah.
5 THE VIDEOGRAPHER: 2:30 p.m.
6 We are off the video record.
7 (Short break.)
8 THE VIDEOGRAPHER: 2:40. We
9 are on the video record.
10 BY MS. GEMAN:
11 Q. Doctor, do you know any of
12 the authors of the article that's been
13 marked as Exhibit 6?
14 A. I do not.
15 Q. Do you see in the
16 conclusions here on the first Page 2390,
17 in the abstract? Do you see where it
18 says, "Conclusions: Patients who
19 previously had a false positive breast or
20 prostate screening cancer test were more
21 likely to engage in future screening"?
22 A. I do.
23 Q. Do you think these authors
24 accurately drew that conclusion from the

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1 data and information they used?
2 A. I -- this is their
3 single-institution dataset. It looks
4 like it matches their tables.
5 Q. Is that consistent with your
6 personal experience as an oncologist?
7 A. I don't order these
8 screening tests. They already have
9 cancer when they come to me.
10 Q. When was the last time in
11 your career that you saw patients who
12 were asymptomatic?
13 A. You mean with respect to
14 cancer?
15 Q. Yes.
16 A. Because I have patients that
17 have completed cancer therapy. They're
18 asymptomatic.
19 In a primary care setting,
20 the last time was 2006.
21 Q. Okay. And do you have --
22 and so your experience in the last
23 16 years has been only with patients who
24 have already had a cancer diagnosis,

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1 correct?
2 A. I practice to the top of my
3 scope as an oncologist.
4 Q. Practice to the top of my
5 scope -- that's figurative, right?
6 A. No. It's actually a term
7 that's used. I did a three-year
8 hematology/oncology fellowship. I use
9 those skills learned to manage cancer
10 patients.
11 Q. So you do not have
12 experience in the last 16 years treating
13 patients who are -- who have not already
14 had a cancer diagnosis?
15 A. The patients that I treat
16 have cancer.
17 Q. So the answer to my question
18 is yes?
19 A. Can you repeat the question
20 again?
21 Q. Sure.
22 You do not have experience
23 in the last 16 years of treating patients
24 who have not already had a cancer

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1 diagnosis, correct?
2 A. Yes.
3 Q. When you -- you indicated
4 that you looked for all the articles that
5 you could find, and you did note that the
6 field is sparse on psychological effects
7 in screening?
8 A. Yes.
9 Q. Okay. Have you ever heard
10 of the Journal of Clinical Oncology?
11 A. Yes.
12 Q. Is that a refereed journal?
13 A. Is that a what?
14 Q. A refereed journal?
15 A. Refereed -- do you mean
16 peer-reviewed?
17 Q. Yes.
18 A. Yes.
19 Q. Okay. Is it a respected
20 journal?
21 A. Yes.
22 Q. Do you recall coming across
23 an article from the Journal of Clinical
24 Oncology entitled "Impact of BRCA1/BRCA2

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1 Mutation Testing on Psychologic Distress
2 in a Clinic-Based Sample"?
3 A. I was -- in my search was
4 looking at screening in asymptomatic
5 patients. I did not look at -- obviously
6 patients with cancer is a different
7 scenario.
8 Q. Well, somebody can have
9 BRCA1 or 2 and be asymptomatic, correct?
10 A. Oh. So these are not cancer
11 patients, these are patients that have
12 been appropriately referred to a cancer
13 risk evaluation program?
14 Q. Well, my question is,
15 somebody can have BRCA1 or 2 and be
16 asymptomatic, correct?
17 MR. KUM: So I'm going to
18 object. Counsel is referring to
19 an article.
20 I think the deponent is
21 entitled to see the article that
22 she's referring to. She already
23 had a question about it. So if
24 you could show it to her.

<p>Page 238</p> <p>1 MS. GEMAN: I'm happy to do 2 that. But I'm asking a sort of 3 question that's irregardless -- 4 true or false irregardless of the 5 article. 6 BY MS. GEMAN: 7 Q. Someone can have BRCA1 or 2 8 and be asymptomatic, correct? 9 A. Yes. 10 Q. And I'll show you the 11 article, and you can tell me if you came 12 across it in your -- in the literature 13 analysis. 14 MS. GEMAN: And for the sake 15 of the court reporter, I'll say 16 this is -- Exhibit 7 will be an 17 article entitled "Impact of 18 BRCA1/BRCA2 Mutation Testing on 19 Psychologic Distressed in a 20 Clinic-Based Sample." 21 (Document marked for 22 identification as Exhibit 23 Teitelbaum-7.) 24 THE WITNESS: I'm the only</p> <p>Page 239</p> <p>1 one without it. 2 MR. KUM: No, the court 3 reporter -- let's go off the 4 record. 5 THE VIDEOGRAPHER: 2:46. We 6 are off the video record. 7 (Brief pause.) 8 THE VIDEOGRAPHER: The time 9 is 2:47. We are on the video 10 record. 11 BY MS. GEMAN: 12 Q. Doctor, did you come across 13 what's been marked as Exhibit 7 in your 14 research for your report? 15 A. I don't think I searched the 16 database for the BRCA population. So I 17 do not -- I did not bring this up. Or if 18 I did, I didn't include it because it 19 didn't seem relevant. 20 Q. I'm going to read the 21 conclusion. 22 "These results" -- and I'm 23 on the first page under conclusion. 24 A. Mm-hmm.</p>	<p>Page 240</p> <p>1 Q. "These results suggest that 2 clinic-based BRCA1/2 testing can lead to 3 psychologic benefits for individuals who 4 receive negative test results. At six 5 months after disclosure those who receive 6 positive or uninformative test results 7 did not exhibit increased psychological 8 distress or perceived risk." 9 Did I read that correctly? 10 MR. KUM: So I'm going to 11 object. Dr. Teitelbaum has asked 12 to read this paper. She hasn't 13 finished reading it. 14 THE WITNESS: I don't think 15 this is screening for cancer. I 16 think this is offering a 17 BRCA1/BRCA2 test, and I will -- to 18 family members of an identified 19 patient with BRCA1/BRCA2. 20 And what I would just say 21 here, is this is an entirely 22 different literature. This is not 23 based on offering cancer-directed 24 screenings.</p> <p>Page 241</p> <p>1 This is simply identifying 2 if they're BRCA1 or BRCA2 or not. 3 In fact, this is in the 4 world of testing and disclosure of 5 testing. It's like an ethics 6 literature kind of thing. 7 I would not have searched 8 about genetic testing in my 9 search. 10 BY MS. GEMAN: 11 Q. So your best recollection, 12 is you didn't do a search that would have 13 uncovered this article? 14 A. I would not have typed in 15 testing for BRCA1/BRCA2 mutations and 16 psychological distress. 17 Q. If you had found it, would 18 you have included it, to the extent that 19 you can answer that counterfactual? 20 A. Well, again to your point, 21 these patients are -- this is just about 22 identifying whether or not they carry a 23 mutation, not about implementing the 24 screening tests.</p>
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<p>Page 242</p> <p>1 So I wouldn't have searched 2 for it, because it wasn't the question 3 being asked. 4 MR. KUM: Doctor, if you 5 want to read it. 6 THE WITNESS: I mean, 7 normally, I don't just read the 8 abstract. I read the entire 9 article. 10 I will, for the purpose of 11 this, because I don't understand 12 why this is relevant, I will just 13 quickly read through the -- 14 MS. GEMAN: We can go off 15 the record if you want and you can 16 read it. 17 THE WITNESS: Okay. That 18 would be great. 19 THE VIDEOGRAPHER: 2:50. We 20 are off the video record. 21 (Short break.) 22 THE VIDEOGRAPHER: 2:58. We 23 are on the video record. 24 BY MS. GEMAN:</p> <p>Page 243</p> <p>1 Q. Doctor, did you have the 2 chance to review what's been marked as 3 Exhibit 7? 4 A. Yes. Thank you for that 5 time. 6 Q. Sure. 7 Did it refresh your 8 recollection as to whether you had or had 9 not seen it before? 10 A. It didn't. 11 Q. Okay. 12 A. I read a lot of JCO, so I'm 13 not sure. 14 Q. JCO is the Journal of 15 Clinical Oncology? 16 A. Yes. 17 Q. And I just wanted to 18 understand something about your earlier 19 testimony. 20 Do you consider testing for 21 BRCA1/2 distinct from screening? 22 A. So it is actually, as of 23 three years ago, standard to test all 24 pancreas cancer patients -- I can only</p>	<p>Page 244</p> <p>1 speak to that -- for BRCA1, BRCA2. 2 PALB2, CHEK2, ATM. 3 There's a high risk. 4 We actually refer them to 5 the cancer risk evaluation program 6 because, as is stated in this article, 7 it's a very emotional decision, and it 8 requires a lot of extensive counseling 9 before. I'll just comment that they 10 think that might be part of that 11 response. 12 This is actually -- the 13 tricky thing here -- and there are other 14 articles that speak to this question, 15 which I'm not completely sure how it 16 refers to my expert letter, but I'll 17 continue. 18 So there -- what I find when 19 I make the referral is there's actually a 20 large amount of patients that choose not 21 to. So this is selecting for a very 22 motivated group. And I would be 23 interested to find out how many didn't. 24 And the reason I think they choose not</p> <p>Page 245</p> <p>1 to -- I mean, I don't know. 2 But I would just say there 3 is a big literature around choosing and 4 around how you inform people and how you 5 counsel people. 6 This is like a field in and 7 of its own. But I am -- you know, I read 8 this, and I would just say this isn't 9 exactly a cancer screening. This is 10 finding out your genetics. And this 11 looks like a self-selected group that was 12 beautifully supported in the 13 decisionmaking. 14 MS. GEMAN: So move to 15 strike all of that as 16 nonresponsive. 17 BY MS. GEMAN: 18 Q. The question is: Do you 19 consider BRCA testing as distinct from 20 screening? 21 MR. KUM: Asked and 22 answered. 23 You can go ahead again. 24 THE WITNESS: I don't see it</p>
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1 as any part of the Preventative
2 task force.
3 It is not a screening test
4 for cancer because not every BRCA1
5 or BRCA2 patient gets cancer. I
6 think it would be a screening for
7 a high risk -- for someone you
8 would include in a high risk
9 population if they were willing to
10 be followed.
11 BY MS. GEMAN:
12 Q. So your testimony under oath
13 is that the BRCA test, is not one that
14 you consider part of a cancer screening
15 because not everyone with BRCA develops
16 cancer; is that correct?
17 A. I mean, this isn't a general
18 test that's offered in an asymptomatic
19 patient population, which is what Dr.
20 Kaplan is addressing. These patients are
21 probably, to your point, also
22 asymptomatic.
23 But it's not a cancer
24 screening test. It is a prerequisite, if

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1 they are positive, to refer them to a
2 high risk cancer screening program.
3 Q. And the cancer risk
4 evaluation program, that's a screening
5 and treatment program or a counseling
6 program?
7 A. We have three of them. We
8 have one, actually, exclusively for BRCA
9 patients with breast and ovarian cancer.
10 We have one for GI cancers. And we have
11 one for, like, all the other weird stuff.
12 And there are different
13 people in charge of each of them. And
14 they help counsel and recommend any
15 Preventative procedures that might be
16 indicated.
17 I don't practice in that
18 clinic, so I'm not really sure of the
19 whole procedure. I just know --
20 Q. You don't consider them
21 screening programs?
22 A. So I don't consider ordering
23 the test a screening program. I consider
24 it a prerequisite for referring to a

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1 screening program.
2 Q. So under your logic, a
3 mammogram is not a screening; is that
4 right?
5 MR. KUM: Objection.
6 Misstates testimony.
7 THE WITNESS: Mammogram is a
8 task force-approved screening test
9 for breast cancer.
10 BY MS. GEMAN:
11 Q. Even though not every
12 abnormality found leads to cancer,
13 correct?
14 A. I'm still trying to figure
15 out the connection. But mammography is a
16 well established test for women within a
17 certain age range to assess for cancer.
18 Q. And my question, which you
19 did not answer, and I will ask you to try
20 to focus on the questions.
21 Not every abnormality found
22 in a mammogram leads to cancer, correct?
23 MR. KUM: Asked and
24 answered. Argumentative.

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1 THE WITNESS: Correct.
2 BY MS. GEMAN:
3 Q. All right. And yet, a
4 mammogram is a cancer screening test,
5 correct?
6 A. Correct.
7 Q. And a pap smear, do you
8 consider that a cancer screening test?
9 A. That's no longer recommended
10 as the same yearly frequency. That's
11 been newly elevated to three. But it is
12 a screening test for changes at the
13 cervix.
14 MS. GEMAN: Move to strike
15 as nonresponsive.
16 BY MS. GEMAN:
17 Q. I do need you to answer my
18 questions. I didn't ask you how frequent
19 or about changes in the interval.
20 A pap smear is a cancer
21 screening test, correct?
22 A. Yes.
23 Q. Not every strand of HPV
24 leads to cancer, correct?

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1 A. Correct.
2 Q. Not every abnormality found
3 in a pap smear leads to cancer, correct?
4 A. Correct.
5 Q. Not every cell that's
6 abnormal in a pap smear leads to a
7 cervical cancer finding, correct?
8 A. Correct.
9 Q. All right. So mammograms
10 and pap smears are cancer screening. But
11 in your view, a test for BRCA is not,
12 because not everyone with a BRCA gene
13 develops cancer. Is that the logic I'm
14 understanding?
15 MR. KUM: Objection.
16 Misstates testimony.
17 THE WITNESS: A BRCA test is
18 to assess someone if they have a
19 hereditary cancer syndrome.
20 BY MS. GEMAN:
21 Q. So it is a cancer screening
22 test in your view or --
23 A. It's a test for hereditary
24 cancer syndrome.

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1 Q. So would you put it in the
2 bucket of screening?
3 A. I -- not in asymptomatic
4 patients.
5 Q. But if it's conducted on --
6 regardless of the person on whom it's
7 conducted, do you consider it a screening
8 test?
9 A. I cons -- not for cancer. I
10 consider it a screening test for
11 hereditary cancer syndrome.
12 Q. And the relevance of --
13 strike that.
14 Do you consider the
15 literature on the psychological distress
16 in connection with BRCA testing relevant
17 to the study of psychological distress
18 associated with other tests that likewise
19 test either for cancer or a precursor to
20 cancer?
21 A. I don't think they're the
22 same thing.
23 Q. Do you have any cite for
24 drawing a distinction psychologically

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1 between those two?
2 A. This is, you know, 20 years
3 of practice. I think this is -- one is
4 testing for a gene that may predispose
5 you and merits referral to a center. And
6 again, this is a single-institution study
7 that only assessed distress in motivated
8 patients.
9 And I think your other
10 question was mammography and pap smear,
11 which is not part of the U.S. task
12 force -- screening task force. But I'm
13 directing your attention to mammography.
14 That is a screening test for cancer.
15 Q. And you mentioned 20 years
16 of practice. How many years -- how many
17 years were you in practice before 2006?
18 A. I was -- before practice.
19 So I was in residency and fellowship and
20 then I came on faculty in 2005 at
21 University of Chicago.
22 Q. Were you ever in private
23 oncology practice?
24 A. No.

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1 Q. Okay. So you've never --
2 even before 2006, it wasn't a regular
3 part of your practice to see patients who
4 might benefit from cancer screening,
5 correct?
6 MR. KUM: Objection. Vague
7 and ambiguous.
8 MS. GEMAN: Fair enough.
9 BY MS. GEMAN:
10 Q. Even before 2006 you weren't
11 seeing patients who had not been
12 diagnosed with cancer?
13 A. Actually, I did have a
14 geriatric primary care practice, 2005 to
15 2006, where I was the attending. And in
16 that setting I was ordering screening
17 according to guidelines.
18 Q. But that was in geriatric
19 primary care, not oncology, correct?
20 A. Right. We don't -- they
21 have cancer by the time they get to us,
22 so we're not ordering screening for
23 cancer.
24 Q. You also express a concern

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1 in your report about overdiagnosis,
2 correct?
3 A. Oh, yes. Mm-hmm.
4 Q. Okay. So I'd like to -- and
5 you used as an example a hypothetical
6 where a person died at 70, regardless of
7 whether they were tested at age 60 or
8 tested at age 67, correct?
9 A. They both die at the same
10 time, the time of diagnosis is different.
11 The age of death is the same.
12 Q. And that was a hypothetical
13 where the authors expressly acknowledged
14 the limitation that the earlier -- "The
15 earlier diagnosis did nothing to change
16 the course of the disease." Is that
17 correct?
18 A. That's what's represented in
19 that cartoon.
20 Q. Okay. So that hypothetical
21 is not speaking at all about instances
22 where testing -- or where catching a
23 cancer earlier can affect the course of
24 the disease, correct?

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1 A. That is not describing those
2 cancers.
3 Q. Okay. And the NCI was not
4 advocating less screening in that
5 article, but instead more sort of
6 numeracy in context for information,
7 correct?
8 A. I think it speaks to
9 individualized recommendation for the
10 patient, doing no harm, making sure that
11 you know what you're testing for, and if
12 it will impact the patient's life.
13 Q. And as an oncologist, if
14 you're presented with an otherwise
15 healthy 60-year-old who does have -- you
16 know, who did have a prostate cancer
17 diagnosis based on the screen, what would
18 you do?
19 A. So to be fair, I wouldn't be
20 seeing that patient because --
21 Q. Oh, yeah. You don't treat
22 prostate.
23 A. Right.
24 Q. Do you have an understanding

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1 of what -- I don't know if it's still
2 called a proctologist? I don't know.
3 A. I'd say urologist.
4 Q. Okay. What would a urologic
5 oncologist -- what might a urologic
6 oncologist do in that scenario?
7 A. Can you repeat the question?
8 Q. Sure.
9 So she's presented with a
10 patient who's an otherwise totally
11 healthy 60-year-old who has prostate
12 cancer that was caught by that screen.
13 A. Mm-hmm.
14 It depends on the stage, the
15 grade. There's very specific treatment
16 algorithms. In truth, urologists, or the
17 most straightforward ones, often start
18 androgen deprivation therapy. And they
19 don't get to a genitourinary oncologist
20 until they have more advanced disease.
21 Q. But the point is there's
22 things that can be done for that
23 60-year-old, right? Unlike in the
24 hypothetical where there was nothing that

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1 could be done.
2 A. If the patient is well
3 enough to treat, there are therapies to
4 be offered.
5 Q. So it would be helpful for
6 that person to know at age 60 -- it would
7 be helpful for someone to know at age 60,
8 who is otherwise healthy, that they have
9 prostate cancer as opposed to only
10 knowing it when it's too late to do
11 anything about it? Can we agree with
12 that?
13 MR. KUM: Objection.
14 Incomplete hypothetical.
15 THE WITNESS: I mean, I
16 think it's completely based on the
17 grade of the tumor. If you have a
18 low grade, and I'm sure you're
19 familiar with the term, watchful
20 waiting.
21 I think -- and again, I'm
22 not doing this, but there's
23 different recommendations, some of
24 which are just observation based

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1 on the grade of the tumor and the
2 stage.
3 I know watchful waiting was
4 something that was accepted in
5 Europe. And we've worked to
6 assess it here through -- and
7 integrate it in the care.
8 If you have an indolent
9 cancer, you may be offered
10 watchful waiting or other
11 therapies.
12 BY MS. GEMAN:
13 Q. And so do you agree that it
14 is helpful for someone to know at age 60
15 that they have prostate cancer as opposed
16 to only learning about it when it's too
17 late to do anything about it?
18 MR. KUM: Asked and
19 answered. Incomplete
20 hypothetical.
21 THE WITNESS: I think,
22 again, I can't answer that without
23 knowing the grade and the other
24 comorbidities.

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1 You said healthy. But, you
2 know, what the life expectancy,
3 the activity level. We assess
4 performance status. There's a lot
5 that goes into a decision to
6 treat.
7 BY MS. GEMAN:
8 Q. Under what circumstances is
9 it better to know at age 60 that you have
10 an early stage cancer as opposed to
11 waiting for seven years until it's too
12 late?
13 A. Well, I think if you have --
14 I think that's exactly the point of that
15 graphic.
16 If you're diagnosed at 63,
17 we may be obliged to do more invasive
18 treatments, but you still die at 70. But
19 if you're not diagnosed at 63, and you
20 have the same indolent cancer, you know,
21 at that time, you have years more of
22 normal uninstrumented or chemotherapy or
23 hormone therapy life.
24 Q. No, no. That hypothetical

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1 was expressly limited to a circumstance
2 where there was nothing the person can
3 do. And the articles -- the authors of
4 that article acknowledge that. So
5 whether you learned at 60, 61, 65 or 67,
6 you were going to die at 70. That was
7 the hypothetical in that article,
8 correct?
9 A. I would have to look back at
10 it.
11 Q. That's your recollection,
12 correct?
13 A. I don't --
14 Q. You just said that a second
15 ago when we were talking about that.
16 A. I just -- I don't know when
17 you die or when you die from or what that
18 discussion is. I'm sorry.
19 Q. You die at 70 from prostate
20 cancer. Do you recall that now?
21 A. I recall the graphic.
22 Q. Okay. What I'm --
23 MR. KUM: Doctor, you can
24 pull your report.

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1 THE WITNESS: Okay. No, no.
2 I agree. You die at 70 from
3 prostate -- that's the premise of
4 that graphic.
5 BY MS. GEMAN:
6 Q. And I'm moving off that
7 hypothetical, which is the situation
8 where -- I'm saying generally, if
9 there's -- if there's possibly something
10 you can do about it, isn't it better to
11 learn that at 60 rather than at 67 when
12 it's too late?
13 MR. KUM: Asked and
14 answered. Incomplete
15 hypothetical.
16 You can answer.
17 THE WITNESS: So you're
18 saying if you are diagnosed at 60,
19 and, I guess -- grade matters, so
20 I don't know how to -- I don't
21 know how to answer this question.
22 It's not exactly how we do
23 the evaluation from an oncology
24 perspective. You can never make

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1 an assessment without looking at
2 the grade and stage of the cancer.
3 I'm not -- if you want to
4 repeat the question.
5 BY MS. GEMAN:
6 Q. Yeah.
7 A. I'm trying to answer. And I
8 apologize.
9 Q. No, it's not something that
10 one would necessarily -- a layperson
11 might imagine to be controversial. If
12 you learn about something at age 60 and
13 can do something about it, isn't that
14 better than learning about it at 67 when
15 there's nothing you can do about it?
16 MR. KUM: Incomplete
17 hypothetical.
18 THE WITNESS: I mean,
19 there's always something you can
20 do about it even if it's later
21 stage. If somebody is not
22 eligible for surgery, it's not
23 curative. They may have different
24 treatments.

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1 I'm not really sure how to
2 answer this. I'm trying to figure
3 out.
4 It's -- there's so many
5 factors. It's not really that
6 black and white because the stage,
7 grade -- you know, how it looks
8 under the microscope tells you how
9 aggressive it's going to be.
10 BY MS. GEMAN:
11 Q. Let's talk about your
12 discussion that overtreatment is a
13 particular concern for lung and prostate,
14 correct, while we're on the subject?
15 A. Yes.
16 Q. You cited Carter for that
17 proposition, correct?
18 A. Mm-hmm.
19 MS. GEMAN: So I'm going to
20 mark as Exhibit 8 -- I'm just
21 trying to help the court reporter
22 by saying where it was in your
23 report -- what's referenced in
24 Footnote 38 of the doctor's

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1 report. "What is Overdiagnosis
2 and Why Should We Take It
3 Seriously in Cancer Screening?"
4 (Document marked for
5 identification as Exhibit
6 Teitelbaum-8.)
7 BY MS. GEMAN:
8 Q. Do you recognize what's been
9 marked as Exhibit 8?
10 A. I do.
11 Q. And you were referring in
12 your report to the -- I'm trying to
13 figure out the page -- to the
14 second-to-last substantive page.
15 At the -- you see with the
16 Figure 2 at the bottom?
17 A. Mm-hmm.
18 Q. And I'm looking at the last
19 full paragraph.
20 MR. KUM: Doctor, just a
21 reminder, you have to give a yes
22 or no.
23 THE WITNESS: Oh, sorry.
24 MS. GEMAN: That's okay.

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1 MR. KUM: You keep saying
2 "mm-hmm." And that's what the
3 court reporter is taking down.
4 THE WITNESS: I apologize.
5 BY MS. GEMAN:
6 Q. And it says, "Some cancers
7 are more likely to be overdiagnosed than
8 others."
9 Do you see that?
10 A. Can you show me where again?
11 Which page?
12 Q. Yes, it's on --
13 A. Page 3?
14 Q. That's a better way to do
15 it. Yes, Page 3.
16 A. Okay.
17 Q. It's a short article. Do
18 you see that?
19 A. That, "Slow-growing cancer
20 is asymptotically present in the body
21 for much longer"?
22 Q. "Some cancers are likely" --
23 "are more likely to be overdiagnosed than
24 others."

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1 Do you see that?

2 A. Yes.

3 Q. Okay. And was this -- and

4 they quote an article from 2013; is that

5 correct?

6 A. Who does?

7 Q. The authors here. They

8 refer to this Estermann.

9 A. Yes.

10 Q. Okay. And these authors

11 note that screening that detects and

12 prompts removal of changes that can later

13 become cancer can occur for colorectal

14 screening, correct?

15 A. That's what it says.

16 Q. Okay. And did the 2013

17 study, the Estermann study that you

18 referenced in your report, raise a

19 concern about overdiagnosis for the seven

20 cancers in -- at issue in this case,

21 other -- that are not lung and prostate?

22 A. Could I see the report? I

23 quoted the seven cancers from

24 Dr. Kaplan's report. I didn't come up

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1 with those seven cancers on my own.

2 I directly referred to his

3 list, which he said he got from his

4 experts.

5 Q. Okay. Does this article

6 talk about liver cancer in this section?

7 A. In which section?

8 Q. The one we're talking about,

9 the one where they identify --

10 A. In Estermann or in this

11 text?

12 Q. In Estermann, which is what

13 you were quoting in your article.

14 A. I need to see the article of

15 Estermann. I don't have the opportunity

16 to comment on an article without the

17 opportunity to read it.

18 Q. Well, I'm just using what

19 you gave us. So I have -- this is

20 literally the document that you cited in

21 your report.

22 A. But you're asking me a

23 question about Estermann.

24 Q. That's right, because that

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1 was the section that you cited in your

2 report that you attributed to these

3 authors.

4 A. I'd like the opportunity to

5 see it.

6 Q. Okay. Well, you didn't cite

7 it in your report, so --

8 A. But you asked me about it.

9 Q. Right, because you ascribe

10 their conclusions to another author.

11 A. Okay. Okay. I'm happy to

12 look at it.

13 Q. Okay. Do you see -- do you

14 see where it says overdiagnosis -- and

15 you quoted this in your article.

16 "Overdiagnosis, or identification of

17 indolent cancer, is common in breast,

18 lung, prostate, and thyroid cancer"?

19 A. Yes.

20 Q. Do you see that?

21 Is liver in that list?

22 A. I don't see it in that list.

23 Q. Okay. Is stomach?

24 A. I don't see it in that list.

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1 Q. Is colorectal?

2 A. I don't see it in that list.

3 Q. Is esophageal?

4 A. I don't see it in that list.

5 Q. Is bladder?

6 A. Bladder is not in that list.

7 Q. Is pancreatic?

8 A. Pancreatic is not in that

9 list.

10 Q. Is blood cancer?

11 A. Blood cancer is not in that

12 list.

13 Q. Okay. And are you aware of

14 research from around 2020 that suggests

15 that less PSA testing was coming at a

16 steep price?

17 A. I'd have to --

18 MR. KUM: Objection.

19 Assumes facts not in evidence.

20 THE WITNESS: Yeah, I have

21 to see the article.

22 BY MS. GEMAN:

23 Q. Well, I'm just -- I'm asking

24 about your sort of general -- general

Page 270

1 knowledge. Do you know if there's talk
2 of changing the PSA testing
3 recommendations?
4 A. I don't know.
5 Q. Okay. And looking at your
6 article -- I'm sorry, looking at your
7 report again, you indicate what -- on
8 Page 15, you say, "The paradox" -- you
9 reference on Page 15 -- and then --
10 A. Oh.
11 Q. Mm-hmm.
12 A. Mm-hmm.
13 MR. KUM: Doctor. Again,
14 please refrain from saying mm-hmm.
15 THE WITNESS: I'm sorry.
16 I'm sorry.
17 MS. GEMAN: No, no. It's
18 okay.
19 THE WITNESS: I'm just
20 trying to keep up with this. It's
21 like a lot of documents. I
22 apologize.
23 BY MS. GEMAN:
24 Q. Sorry. The good news is

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1 this is back to your report.
2 You state in the last
3 sentence of the full -- sorry, the
4 second-to-last full paragraph on Page 15
5 that, "Screening is less likely to find
6 the aggressive, rapidly progressive
7 cancers that cause the greatest mortality
8 and morbidity."
9 Do you see that?
10 A. Yes.
11 Q. And when I read the articles
12 that were referenced by you, they weren't
13 suggesting that the screens, like, catch
14 a small tumor and miss a large tumor, but
15 instead that -- instead that the those
16 tumors are faster growing, and by the
17 time -- and people are more likely to
18 have symptoms that present?
19 A. So just one thing, back to
20 the list. The cancers you mentioned,
21 only colon cancer has an indicated
22 screening option.
23 So just to speak to those
24 cancers on the list, the only one that --

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1 the only four that we have national
2 guidelines are -- with identified
3 screening tests are prostate, lung, colon
4 and -- I'm getting tired -- thyroid. Not
5 thyroid. Prostate, lung, and breast.
6 And there are specific
7 recommendations not to screen for
8 thyroid, pancreas.
9 So I think the distinction
10 here is people are trying to screen for
11 them or trying to test for them, and
12 that's not sort of the indication.
13 They're actually recommended against.
14 So -- and you actually said
15 it perfectly, that some cancers have a
16 different biology and may be very
17 aggressive and don't always obey the
18 general carcinogenesis timeline of
19 decades. And perhaps there is an
20 aberrant cell that at year seven in your
21 screening interval of ten years appears
22 and grows rapidly.
23 And I think the point here
24 is that using established protocols of

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1 recommendations in that individual
2 patient, the screening would not catch
3 that cancer.
4 Q. I see. Because under the
5 recommended intervals, it just wouldn't
6 catch it. It's not as though if the
7 person had a test on year eight, that it
8 would miss it?
9 A. Right.
10 Q. It's just they wouldn't have
11 been screened at all?
12 A. They wouldn't have been
13 screened. And again, this is -- there's,
14 you know, individuals and then there's
15 population science, and the guidelines
16 are based on population.
17 Q. Are you against endoscopies?
18 A. Upper or lower?
19 Q. Upper.
20 A. Against? I'm not against
21 endoscopies.
22 Q. Can -- I wanted to come back
23 to a subject about which we had some
24 colloquy earlier.

<p style="text-align: right;">Page 274</p> <p>1 Which tests do you use that 2 are not FDA approved, to your knowledge? 3 A. I don't know. 4 Q. Do you have knowledge of the 5 FDA approval status of every test that 6 you use? 7 A. The -- I mean, I have a list 8 of tests that I can order from. 9 I don't -- you know, usually 10 the ones that are outside the realm are 11 common boxes that we have to order 12 separately. The ones that I can click in 13 my order panel are FDA approved. 14 And again, I'm ordering very 15 standard tests to monitor the toxicities 16 of cytotoxic chemotherapy. So that's the 17 reference. 18 Q. What are the tests that you 19 use that you have to order separately? 20 A. I could order Signatera, as 21 I said, which is FDA approved. Because 22 of the controversy, I only order it 23 within the context of a clinical trial. 24 I order Next Generation</p>	<p style="text-align: right;">Page 276</p> <p>1 minute ago -- 2 A. Mm-hmm. 3 Q. -- a minute ago, you said 4 you weren't sure about the approval 5 status of some of your tests. 6 A. I said I know what isn't. 7 But I don't know -- you know, I order 8 very -- CBC is FDA approved. Liver panel 9 is FDA approved. I order very standard 10 tests. 11 The question for me comes 12 when it's a non-standard test. And 13 that's when the FDA approval is relevant 14 to me. 15 Q. And what, in addition to the 16 genomic sequencing that you mentioned, 17 are there any other non-standard tests 18 that you use? 19 MR. KUM: Other than the 20 Signatera that she also mentioned 21 to you. 22 MS. GEMAN: I think the 23 doctor said she does not use 24 Signatera.</p>
<p style="text-align: right;">Page 275</p> <p>1 Sequencing, which is an indicated 2 indication to find out a mutational 3 status of the tumors, to see if there's a 4 targeted therapy. So like a lock and a 5 key, that's actually a genomic mutation 6 analysis of the tumor. 7 These are things that we 8 have in our lab. So I don't, and I 9 don't -- you know, I know things that 10 aren't, but I don't know how to say what 11 I do. I have -- 12 Q. I'm sorry. I -- 13 A. I know what isn't FDA 14 approved, and I know what is. And I hope 15 that you picked up that even if it is, I 16 make an informed decision. Even if it's 17 available, it's really easy to order a 18 test. 19 But again, you have to know 20 what to do with the test and that speaks 21 to pretest probability and efficacy and 22 what you would do for it. 23 Q. But you just said, "I know 24 what isn't FDA approved." But then a</p>	<p style="text-align: right;">Page 277</p> <p>1 THE WITNESS: I use it 2 within the context of a clinical 3 trial. 4 BY MS. GEMAN: 5 Q. Clinical trial, right. 6 A. So I have certainly ordered 7 it. 8 Q. Okay. 9 A. I just don't feel 10 comfortable outside of the context of a 11 clinical trial. 12 I order Next Generation 13 Sequencing, which is indicated. That's 14 mostly what I order. 15 I actually don't order 16 genetic testing of patients for 17 hereditary cancer syndrome, to your 18 point. I actually refer them out, so 19 that they have all of the supportive care 20 that goes along with that recommendation, 21 including a genetic counselor and all of 22 those things. 23 Q. And why do you use Next Gen 24 Sequencing if it isn't approved?</p>

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1 A. I didn't say it isn't
2 approved. I said it's indicated.
3 MR. KUM: I was going to
4 object. That misstates her
5 testimony.
6 MS. GEMAN: Oh, I may have
7 misunderstood.
8 BY MS. GEMAN:
9 Q. Because I had asked what
10 tests you use that aren't FDA approved,
11 you included Next Gen Sequencing among
12 your answer. So I may have
13 misunderstood.
14 MR. KUM: Actually, your
15 question was non-standard tests.
16 That's not the same as --
17 MS. GEMAN: But the doctor
18 also answered the previous
19 question, which was not FDA
20 approved. So let's just clarify
21 this.
22 BY MS. GEMAN:
23 Q. Next Gen Sequencing is
24 approved by the FDA?

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1 A. Yes.
2 Q. Okay. And Signatera is not?
3 A. It is approved.
4 MR. KUM: Is.
5 BY MS. GEMAN:
6 Q. Is approved. Okay.
7 Are there tests that you use
8 that are not FDA approved?
9 MR. KUM: Objection. Asked
10 and answered.
11 You can answer again.
12 THE WITNESS: I don't know.
13 I don't think, unless I know it
14 has approval, which usually means
15 when you can easily order it, and
16 I know the indication that I'm
17 ordering it for, then I order it.
18 BY MS. GEMAN:
19 Q. Okay. I understand better
20 now.
21 So there are tests that you
22 use that you know are FDA approved. And
23 there are tests that you use about which
24 you are agnostic as to the FDA approval

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1 status?
2 MR. KUM: Actually.
3 Objection. Misstates testimony.
4 She never says she uses
5 non-FDA-approved tests.
6 MS. GEMAN: Well, actually
7 you're testifying for the witness.
8 MR. KUM: I'm not. She
9 actually -- you asked this
10 question several times earlier,
11 and now you're asking this
12 question again.
13 So you can go ahead and ask
14 it again.
15 BY MS. GEMAN:
16 Q. Is this correct: You use
17 some tests that are FDA approved. Not
18 all tests that are FDA approved are ones
19 that you use, obviously. You also use
20 some tests where you are agnostic as to
21 whether they are approved.
22 MR. KUM: Objection.
23 Misstates testimony.
24 THE WITNESS: I order basic

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1 tests, CBC, liver panel, kidney
2 panel. Those are the majority of
3 tests that are -- they are so long
4 standing, I'm not sure of their
5 FDA status.
6 But they are certainly
7 indicated and recommended, not
8 just in all of the 20 years that
9 I've been doing this, but the NCCN
10 guidelines certainly indicate that
11 we should be testing all of those
12 things to safely treat our
13 patients.
14 BY MS. GEMAN:
15 Q. Are there any tests that you
16 use, other than those where you are
17 agnostic about the FDA approval status?
18 MR. KUM: Objection. Vague
19 and ambiguous.
20 THE WITNESS: I don't order
21 many tests.
22 BY MS. GEMAN:
23 Q. Okay.
24 A. I order the same panel.

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1 MS. GEMAN: Okay. Let's
2 take a brief break if that's all
3 right.
4 THE VIDEOGRAPHER: 3:32. We
5 are off the video record.
6 (Short break.)
7 THE VIDEOGRAPHER: 3:49, we
8 are on the video record.
9 BY MS. GEMAN:
10 Q. Doctor, have you been
11 designated as an expert in any litigation
12 other than this one where you're a
13 proposed expert?
14 A. I mentioned the two
15 depositions.
16 MR. KUM: She means as an
17 expert, like a paid expert. Not
18 just any depos.
19 THE WITNESS: Oh, I did some
20 in residency, like a review of
21 records.
22 BY MS. GEMAN:
23 Q. Okay. So when you were a
24 resident, you were designated -- or do

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1 you know if you were designated as a
2 testifying expert in any of those cases?
3 A. It was more -- I think -- it
4 was a long time ago. I think it was more
5 kind of a review of records from a
6 medical standpoint so that the attorneys
7 could make a decision whether or not they
8 wanted to pursue.
9 Q. In a medical malpractice?
10 A. In a medical malpractice.
11 Q. Did any of those cases
12 involve cancer?
13 A. I don't remember. I did --
14 I did maybe three. I didn't -- I was too
15 tired as a resident to really do them
16 with any frequency, so I stopped.
17 Q. Do you remember the subject
18 matter?
19 A. I don't.
20 Q. Are you -- other than this
21 case -- and this is a yes/no question.
22 Have you been retained as a
23 consultant or testifying expert in any
24 other cases?

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1 MR. KUM: You mean like
2 ever, right?
3 MS. GEMAN: Yeah.
4 THE WITNESS: Yes, I was
5 asked -- although it never went
6 anywhere. I was asked to review a
7 record about a patient with a
8 diagnosis of pancreas cancer, and
9 I think it was a missed diagnosis
10 on imaging.
11 BY MS. GEMAN:
12 Q. For which side were you
13 asked to review records?
14 A. The patient, is the
15 plaintiff, right?
16 For the defense.
17 Q. For the defense. Did you
18 conclude that there had been a missed
19 diagnosis?
20 A. It was apparent on the
21 imaging. It was for a different
22 indication, but it was present.
23 Q. And do you know if they
24 settled?

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1 A. I know they settled.
2 Q. Were you ever disclosed to
3 the court, if you know?
4 MR. KUM: Don't guess.
5 THE WITNESS: I don't know.
6 Sorry.
7 BY MS. GEMAN:
8 Q. And presently, are you
9 working on any cases as an expert other
10 than this one?
11 A. Not a single one.
12 MS. GEMAN: All right. I
13 have nothing further.
14 BY MS. GEMAN:
15 Q. Actually, I'm sorry. I
16 didn't mean that as a bait and switch,
17 although I'm sure it sounded like it. I
18 apologize. I have just a couple more.
19 Did you just -- did you
20 discuss with your counsel -- or with this
21 counsel the question and answers that
22 they are going to ask now?
23 MR. KUM: I'm going to
24 object that --

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1 BY MS. GEMAN:
2 Q. Yes or no?
3 MR. KUM: -- it invades the
4 attorney work product privilege,
5 and I'm going to instruct you not
6 to answer.
7 THE WITNESS: Okay.
8 MS. GEMAN: All right. Pass
9 the witness.
10 Thank you for your time.
11 THE WITNESS: Thank you.
12 THE VIDEOGRAPHER: Let's go
13 off the record.
14 MR. KUM: Yeah.
15 THE VIDEOGRAPHER: 3:52. We
16 are off the video record.
17 (Brief pause.)
18 THE VIDEOGRAPHER: 3:54. We
19 are on the video record.
20 - - -
21 EXAMINATION
22 - - -
23 BY MR. KERNER:
24 Q. Dr. Teitelbaum, good

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1 afternoon. It's been a relatively long
2 day. So I will try keep this as short as
3 possible. I just have a few questions.
4 And let's see if we can get through them.
5 Am I correct that you work
6 at Penn?
7 A. Yes.
8 Q. And you teach at Penn?
9 A. Yes.
10 Q. What's your title there?
11 A. I am the Deenie Greizer and
12 Daniel Haller associate professor of
13 gastrointestinal malignancies, which is
14 an endowed chair. And my current title
15 is associate professor of clinical
16 medicine.
17 Q. Are you also involved in the
18 Pancreatic Cancer Research Center there?
19 A. Oh, yeah. I'm the clinical
20 director of the Penn Pancreatic Cancer
21 Research Center.
22 Q. What do you do in connection
23 with that?
24 A. Oh, that's a really fun part

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1 of my job.
2 So we have -- we get to -- I
3 work with the lab researchers and the
4 translational researchers, and we look
5 through our portfolio of clinical trials
6 and research questions, and we help
7 direct the efforts and the funds towards
8 those projects.
9 One of the things that we
10 like to do the most, actually, are
11 investigator-initiated trials, where --
12 you know, there's big, collaborative
13 trials but you're always interested in
14 independent research.
15 Q. You said that you direct the
16 efforts and the funds towards those
17 projects?
18 A. We work together to figure
19 it out. And I also -- I get money as
20 part of my endowed chair that I get to
21 put to clinical trials. So every year I
22 get to pick a study.
23 Q. Not money that goes to you?
24 Money that goes to the trials?

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1 A. I don't get money from the
2 endowed chair. I actually direct it all
3 to interesting research projects that
4 need funding.
5 Q. Okay. I think you just said
6 that you were an associate professor?
7 A. Yes.
8 Q. That's your current title?
9 A. Yes.
10 Q. Do you also treat patients
11 in a clinical setting?
12 A. Oh, yes. I practice
13 primarily -- exclusively in the cancer
14 clinic.
15 Q. Can you tell me a little bit
16 about your clinical experience?
17 A. Oh, it's busy.
18 You know, I will see new
19 patients that are, you know, first
20 diagnosis with a difficult cancer. And I
21 do a lot of the education about their
22 diagnosis, prognosis, and treatment
23 plans.
24 I see a large number of

<p style="text-align: right;">Page 290</p> <p>1 patients in consultation and render an 2 opinion, and then will often work with 3 their treating physician to help guide 4 their care. 5 I present every patient in 6 our multi-disciplinary clinic. We have a 7 multi -- interdisciplinary clinic with 8 surgery, radiation -- radiation oncology, 9 all the disciplines, pathology. 10 And we -- I present every 11 one of my patients to make sure they have 12 the best treatment options. 13 And I run the 14 pancreatobiliary multidisciplinary 15 conference every Wednesday. 16 I also have a large percent 17 of patients that I'm actively treating 18 with chemotherapy. So they will often 19 come every week or every other week, 20 depending on their regimen, and then 21 monitor them with scans and -- at 22 prescribed intervals. 23 And then I have patients 24 that are referred after surgery who meet</p>	<p style="text-align: right;">Page 292</p> <p>1 submit that regimen for insurance 2 coverage and do all the planning, chemo 3 teaching. 4 And again, if a patient is 5 on regimen, I don't present them unless 6 there's a clinical question. But if a 7 patient progresses on a therapy or 8 doesn't tolerate it, then I'll put them 9 up to tumor board again to get input. 10 Q. Okay. In the ordinary 11 course of your care and treatment of your 12 patients, are you required to weigh the 13 risks and benefits of administering 14 certain tests? 15 A. I have to think about every 16 test that I offer. And one of the most 17 important things is I have to make sure a 18 patient of mine is well enough. 19 These are cancer patients. 20 They are vulnerable. A lot of them 21 are -- for example, colon cancer and 22 quite well and working. But I still have 23 to make sure that it's safe and tolerable 24 for them.</p>
<p style="text-align: right;">Page 291</p> <p>1 the indications for benefit of -- it's 2 called -- we call it adjuvant therapy, 3 postoperative therapy. And the goal of 4 that therapy is to reduce the risk of 5 recurrence. So it's enhancing their 6 chance for care. 7 Q. Okay. And I think you've 8 sort of just answered this. But I'm 9 going to ask it anyway. So feel free to 10 tell me you've just answered it. 11 In the ordinary course of 12 your care and treatment of your patients, 13 have you been responsible or are you 14 responsible for determining an 15 oncological care plan for those patients? 16 A. Oh, I have to devise an 17 oncologic care plan for each patient. We 18 always try and put patients on clinical 19 trial because you always want to see if 20 you can improve the standard of care 21 generally. 22 And by definition, if you're 23 enrolling them on trial or you're putting 24 them on standard therapy, you have to</p>	<p style="text-align: right;">Page 293</p> <p>1 Q. And so the short answer to 2 my question was yes? 3 A. Yes. 4 Q. Okay. And my follow-up 5 question, which you started to answer, 6 is, what analysis do you conduct in 7 determining whether a particular test or 8 procedure is appropriate for a particular 9 patient? 10 A. Sure. So performance status 11 is really the language of oncology. We 12 have EGOG performance status or Karnofsky 13 where we actually grade the wellness of 14 the patient. 15 And for example, if you have 16 zero symptoms, you're a performance 17 status zero. 18 If you are -- have some 19 symptoms day to day, but you're largely 20 functional, you are a one. 21 If you're up and out of bed 22 50 percent of the time but very affected 23 by your cancer, you're a two. 24 If you're in bed or chair</p>

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1 greater than 30 percent, you are a three.
2 And if you're bedbound,
3 you're a four.
4 And this does two things.
5 We use those criteria to assess whether
6 or not a patient is appropriate for
7 clinical trial. Only zeros and ones go
8 to trial. But we also track the wellness
9 and well-being of the patient.
10 Q. Okay. Now, in assessing the
11 risks and benefits of a particular test
12 or procedure, have you reviewed medical
13 studies to help analyze those risks and
14 benefits?
15 MS. GEMAN: Objection.
16 THE WITNESS: I review -- I
17 try to be as informed as I can
18 about every test I'm offering, be
19 it a lab or a procedure. In the
20 same context, I strive to be
21 informed by the therapies that I
22 give.
23 BY MR. KERNER:
24 Q. And in connection with that,

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1 you'll review medical literature?
2 A. Absolutely, or NCCN.
3 Q. All right. With respect to
4 this matter, how did you go about looking
5 into the question of whether Dr. Kaplan's
6 medical monitoring plan was appropriate
7 for the proposed class?
8 A. So, you know, first I went
9 to the standard of care, the national
10 standard of care guidelines for
11 asymptomatic patients.
12 And then I looked at his
13 recommendations. And I think, as you can
14 see in my expert report, actually went
15 through each test. And, for example
16 history as part of standard screening, I
17 commented on what is and what isn't in
18 the primary care setting.
19 And then I discussed what I
20 agreed with or what I had concerns about.
21 Q. And did you conduct a
22 literature search in connection with your
23 analysis?
24 A. Yes.

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1 MS. GEMAN: Objection.
2 BY MR. KERNER:
3 Q. How did you do that?
4 MS. GEMAN: Objection.
5 Asked and answered.
6 THE WITNESS: I did a
7 literature search.
8 BY MR. KERNER:
9 Q. And how did you do that?
10 A. I --
11 MS. GEMAN: Same objection.
12 BY MR. KERNER:
13 Q. You can answer.
14 A. -- looked at U.S. --
15 Q. How did you conduct the
16 literature search?
17 A. Oh, I looked up the task
18 force recommendations, and then I looked
19 at each test with the data to see if
20 there was data supporting it.
21 Q. In addition to -- in
22 addition to the materials on your list of
23 materials considered in your report, did
24 you also employ any general or background

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1 knowledge or experience that you might
2 have?
3 MS. GEMAN: Objection.
4 THE WITNESS: I look at
5 everything with my clinical
6 experience. I can't -- you know,
7 I've done this for 20 years. So
8 my personal experience, I can't
9 not have that as I evaluate a
10 regimen or a patient. It's who I
11 am.
12 BY MR. KERNER:
13 Q. Okay. And after employing
14 the methodology -- excuse me -- that you
15 employed, did you reach a conclusion as
16 to whether Dr. Kaplan's medical
17 monitoring plan is appropriate for the
18 proposed class members?
19 MS. GEMAN: Objection.
20 THE WITNESS: I do not think
21 it's appropriate for these class
22 members or anybody.
23 BY MR. KERNER:
24 Q. Why not?

<p>Page 298</p> <p>1 A. There are a lot of tests 2 that are risky that have no indication, 3 that would cause significant harm. And 4 You know, we -- we actually, you know, 5 take an oath to do no harm. 6 And I think the magnitude of 7 harm that recommending this regimen would 8 be profound. 9 Q. Okay. And what did you rely 10 on to form that conclusion or that 11 opinion? 12 MS. GEMAN: Objection. 13 THE WITNESS: Again, I 14 reviewed each of the tests. I 15 looked at what the indications 16 were for and what the indications 17 weren't for. 18 I mean, I even worry, again, 19 that you know, some of the 20 invasive tests these patients 21 wouldn't even be candidates for, 22 based on their cardio -- 23 significant cardiovascular 24 disease, like heart failure.</p> <p>Page 299</p> <p>1 So -- but even without those 2 comorbidities, I wouldn't 3 recommend this for any person. 4 BY MR. KERNER: 5 Q. And your conclusions are all 6 stated in your report, correct? 7 A. Regarding the medical 8 monitoring? 9 Q. Yes. 10 A. They are all stated. 11 Q. Thank you. 12 Do you have an opinion as to 13 whether Dr. Kaplan's proposed medical 14 monitoring plan would increase longevity 15 for any individual proposed class member? 16 A. I have zero clue if it 17 would. I worry, conversely, about the 18 real harm it might have for a patient. I 19 mean, for example, if you do a 20 transrectal ultrasound biopsy, the risk 21 of sepsis is one in a thousand, which is 22 significant. If -- I think we mentioned 23 before, colonoscopy, risks from the 24 procedure is 0.8. But if you have a</p>	<p>Page 300</p> <p>1 medically ill or older patient and you 2 put them through a colonoscopy prep, you 3 know, causes nausea, vomiting, 4 dehydration, and diarrhea -- and we used 5 to put these patients in the hospital 6 because the preps are so onerous for sick 7 or older adults. 8 And, you know, I don't know 9 that there's a literature, but I would 10 worry if someone fell. It's not going to 11 say prepping for a colonoscopy on their 12 hospital admission or death certificate. 13 It would say fall. 14 So I don't know if all of 15 the morbidity is represented in that 16 procedure risk data. 17 Q. Okay. You mentioned 18 colonoscopy. And I think you mentioned 19 perforation as well. 20 You were asked some 21 questions earlier today by counsel as to 22 whether there was a trend in the last 23 30 years of a decrease in perforations. 24 Do you remember that</p> <p>Page 301</p> <p>1 questioning? 2 A. I do. 3 Q. And I think you -- and I'm 4 paraphrasing, so I apologize if I don't 5 quote you exactly. I think you said 6 something like you weren't familiar with 7 that data. 8 Are you familiar with the 9 data of perforations in 2022? 10 A. Given that Dr. Kaplan is 11 recommending that test in 2022, I looked 12 at the current data, so I would know the 13 risk. 14 Q. And you're familiar with 15 that now? 16 A. I was always familiar with 17 that. I didn't think a trend was 18 relevant. 19 Q. We're almost there, 20 Dr. Teitelbaum. 21 You were also asked some 22 questions earlier today -- you talked 23 about adherence, the concept of 24 adherence.</p>
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1 A. Yes.

2 Q. And I think you were asked

3 whether you knew the specific adherence

4 of the individual class members, the

5 proposed class members?

6 A. Correct.

7 Q. I think you said that you

8 didn't know the specific class members'

9 adherence, correct?

10 A. I have no Epic -- I have no

11 access to their pharmacy data or pill

12 boxes.

13 Q. Okay. You do -- you are

14 aware of the adherence numbers in the

15 general population, correct?

16 A. Yes.

17 Q. And what are they again?

18 A. Adherence is generally

19 around 50 percent. And just to be clear,

20 a person that is taking 80 percent of

21 their medications is considered adherent.

22 And that means that you're essentially

23 missing one day -- one week every month,

24 right.

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1 So just to sort of establish

2 what the standard in the general

3 population is.

4 Q. Okay. And again, just the

5 concept of adherence, tell us very

6 quickly what that is.

7 A. It's interesting. It used

8 to be compliance. But that's a little

9 judgy, so we call it adherence now. And

10 it's if you're prescribed a pill, do you

11 take it at the prescribed dose, and do

12 you stop it on your own. A lot of

13 patients stop it on their own. It's

14 exactly that, adherence to the

15 prescription as written.

16 Q. Okay. And so 50 percent

17 adherence would mean to a layperson that

18 the individual taking the medication or

19 prescribed the medication complies or

20 takes the medication 50 percent of the

21 time, correct?

22 A. Adheres 50 percent of the

23 time. People -- nobody finishes their

24 antibiotics. Like I've been guilty of

Page 304

1 that. You know, a lot of people are not

2 adherent to their medications.

3 Q. Do you have any reason to

4 think that the adherence of the purported

5 class is any different than the general

6 population?

7 A. I would imagine it is. This

8 was --

9 Q. You imagine it is what?

10 A. -- a general medicine

11 population.

12 Q. Would you imagine that it is

13 different?

14 A. That it is the same.

15 Q. As the general population?

16 A. I would imagine it is the

17 same as the general population.

18 Q. Okay. I'm sorry.

19 There was some testimony

20 earlier today and some questioning from

21 counsel about the levels of nitrosamines

22 in the valsartan-containing drugs.

23 Do you remember that?

24 A. Yes.

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1 Q. Is the level of nitrosamine

2 in valsartan-containing drugs relevant to

3 your opinion concerning Dr. Kaplan's

4 medical monitoring protocol?

5 A. Completely irrelevant.

6 Q. Why?

7 A. It doesn't change the

8 screening recommended. We don't change

9 screening just on the basis of an

10 exposure without evidence that -- and

11 there's only one exposure-driven task

12 force recommendation for screening. And

13 that's lung cancer, 20 years, ages 55 to

14 80. That is the only exposure-driven

15 recommendation for screening.

16 Q. Okay. Dr. Teitelbaum, would

17 an internist assessing cancer screening

18 for an asymptomatic patient in a clinic

19 refer to the NCCN guidelines for

20 screening recommendations?

21 MS. GEMAN: Objection.

22 Objection. Incomplete

23 hypothetical.

24 MR. KERNER: Sorry.

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1 BY MR. KERNER:
2 Q. You can answer.
3 A. Oh, the National
4 Comprehensive Cancer guidelines?
5 Q. Yes.
6 A. I don't even think they'd
7 even know what they are.
8 Q. So is it your testimony that
9 in your opinion the internist would not
10 refer to the NCCN?
11 A. They would not --
12 MS. GEMAN: Same objection.
13 THE WITNESS: -- refer to
14 the NCCN guidelines.
15 BY MR. KERNER:
16 Q. Okay. Dr. Teitelbaum, in
17 Dr. Kaplan's deposition -- and I think
18 you may have referred to this earlier, he
19 talked about or he testified that he
20 would order a PSA on a healthy
21 95-year-old man.
22 Do you recall reading that
23 testimony?
24 A. Yes.

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1 Q. Would you order a PSA on a
2 healthy 95-year-old man to screen for
3 prostate cancer?
4 A. Never.
5 Q. Why not?
6 A. First of all, we know --
7 I've seen the numbers everywhere from 50
8 to 90 percent for patients 80 and above,
9 that they all have prostate cancer. They
10 don't -- at autopsy, I remember
11 50 percent of 80-year-olds have prostate
12 cancer. It's not what they die from.
13 It's what they die with.
14 And then again, it speaks --
15 you know, people don't think ordering a
16 test is risky. But if you order a test,
17 you have to think about what you're going
18 to do.
19 So you sort of open the can
20 of worms that the PSA is high and the
21 patient has prostate cancer, even though
22 it's unlikely to impact them in the
23 entire course of their life.
24 And so if you get that test,

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1 what are you going to do next? Are you
2 going to refer them for a transrectal
3 ultrasound biopsy, which is, again, very
4 difficult to sterilize, because you're
5 going through the rectum. I think of
6 E. coli when I think of rectal organisms.
7 The act of the biopsy can
8 cause incontinence, impotence, blood in
9 your urine, blood in your sperm, in
10 addition to bleeding.
11 And so it's an invasive
12 test. The risk of sepsis is one in a
13 thousand. And the risk goes up if you're
14 older or if you have any medical issues
15 or you're on anticoagulants.
16 So then if you get -- so
17 then if you put the patient through that
18 test, then you have to figure out -- and
19 it's positive, are you going to treat
20 them? Again, I mentioned watchful
21 waiting as an option. But it's really
22 difficult to say to them, watchful
23 waiting, when you've put them through
24 this invasive test.

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1 Some people think, oh, you
2 can put them on androgen deprivation
3 therapy, Lupron, but then the risk is
4 muscle wasting, loss of bone density, and
5 cognitive impairment, which any
6 95-year-old can ill afford. Almost
7 certainly not going to give them
8 chemotherapy and will not be offered
9 surgery.
10 So you've put a patient
11 through the anxiety of having a diagnosis
12 which is unlikely to affect them in their
13 lifetime, for which the therapies are
14 potentially incredibly toxic.
15 So that is actually not just
16 the rationale why not to order -- I think
17 he said 80-year-old, 90-year-old.
18 95-year-old, but really the question of
19 ordering it all.
20 MR. KERNER: Okay.
21 Dr. Teitelbaum, thank you very
22 much for your time. I have
23 nothing else.
24 - - -

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1 EXAMINATION
2 - - -
3 BY MS. GEMAN:
4 Q. Dr. Teitelbaum you spoke a
5 little bit about the ACOG grades?
6 A. ECOG. It's the European --
7 it's the European Cooperative Oncology
8 Group.
9 Q. Okay. And are those grades
10 different for each person or is it the
11 same grading scale but different people
12 can have different grades?
13 A. It's unique to a patient
14 with cancer.
15 Q. But is it the same grading
16 scale applied to all patients with cancer
17 and different people can have different
18 grades?
19 A. Yes. Mm-hmm.
20 Q. Okay. And you said that you
21 reviewed medical literature, right, when
22 you were doing your research for this
23 report, correct?
24 A. Yes.

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1 Q. And that medical literature
2 was done on studies of populations,
3 correct, groups of people?
4 A. Can you clarify? I don't --
5 MR. KUM: Objection. Vague
6 and ambiguous.
7 THE WITNESS: -- understand
8 your question.
9 BY MS. GEMAN:
10 Q. Sure.
11 None of -- none of those
12 articles did a study on just one person,
13 correct?
14 MR. KERNER: Let me
15 interject for one second. I
16 apologize can we go off the record
17 for one second and not leave the
18 room.
19 THE VIDEOGRAPHER: Stand by.
20 4:14. We are off the video
21 record.
22 (Brief pause.)
23 THE VIDEOGRAPHER: 4:15. We
24 are on the video record.

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1 BY MS. GEMAN:
2 Q. None of those articles did a
3 study on just one person, correct?
4 A. I don't recall looking at a
5 case report. So I would say no.
6 Q. Typically, the medical
7 literature rises out of studies on groups
8 of people together, correct?
9 A. Yes.
10 Q. Okay. You weren't
11 suggesting that 0.8 percent of people die
12 from a colonoscopy, were you?
13 MR. KUM: Objection.
14 Misstates testimony.
15 THE WITNESS: I said the
16 complication rate. And you know,
17 it's broad. It can include a
18 large range of complications that
19 I listed in my expert letter.
20 BY MS. GEMAN:
21 Q. So the answer is you weren't
22 suggesting that .8 percent of the people
23 die, correct?
24 A. No.

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1 Q. All right. And would you
2 advise against someone from getting a
3 colorectal screening on the basis that
4 they might be kind of dizzy from the
5 treatment and fall?
6 MR. KUM: Objection.
7 Incomplete hypothetical.
8 THE WITNESS: I -- as you
9 can tell, Dr. Kaplan and I, when
10 we're doing the standard of care,
11 you have to make sure that the
12 patient can tolerate the prep.
13 That's actually really important,
14 and be well enough to undergo a
15 procedure with sedation, if that's
16 your question.
17 BY MS. GEMAN:
18 Q. So my question was, would
19 you advise against someone from getting a
20 colorectal screening on the basis that
21 they might fall?
22 MR. KUM: Same objections.
23 THE WITNESS: To your point,
24 again, that's an individual

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1 patient, and you'd have to
2 obviously weigh the risk of your
3 suspicion that the patient had --
4 in my field it would be the
5 suspicion that there's bleeding or
6 some sort of issue with the -- you
7 know, if a patient can't get a
8 ride home from their prep, if they
9 can't get the prep. There's a lot
10 that goes into that.
11 BY MS. GEMAN:
12 Q. And you recall Dr. Kaplan
13 talking about the distinction between
14 screening and treatment, correct?
15 A. I think -- I don't remember
16 exactly. But I'm sure that that's the
17 phraseology.
18 Q. And there is a difference,
19 correct?
20 A. Oh, yes.
21 Q. You quoted a 50 percent
22 adherence rate. And that's across all
23 medications?
24 A. I will have to refer to that

Page 315

1 primary article.
2 Q. Well, you just answered
3 questions to Mr. Kerner about it. To
4 your knowledge, is that across all
5 medications?
6 A. I think it is not medication
7 specific. I think it's a general
8 principle of prescription adherence.
9 Q. I'm sorry. Prescriptions
10 for medications?
11 A. Medications.
12 Q. So it is medication
13 specific?
14 A. It's -- oh, I see what
15 you're saying. I thought it was like a
16 specific medication. It's a prescribed
17 medication.
18 Q. So it includes birth control
19 pills?
20 A. I don't remember seeing that
21 specifically. So I can't say.
22 Q. Do you have any reason to
23 believe that's excluded?
24 A. I don't know.

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1 Q. Do you acknowledge that it
2 includes antibiotics?
3 A. I would have to look at the
4 article to see.
5 As you said, they analyze
6 study groups. And what their methods
7 were, I don't know if it included
8 short-term therapies or preventive
9 therapies. I'm not sure. I would have
10 to look at that article and look at the
11 study group and how the study was done.
12 Q. So you have absolutely no
13 reason or even enough knowledge about
14 that figure to think that it applies to
15 the -- this particular class of valsartan
16 patients, correct?
17 MR. KUM: Objection.
18 Misstates testimony.
19 THE WITNESS: I reviewed the
20 literature. This was the figure I
21 read and quoted in the general
22 population. I use the general
23 population as the metric in this
24 sort of subspecialty area of

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1 adherence.
2 BY MS. GEMAN:
3 Q. Do you think that's valid
4 methodology to say that a statistic that
5 includes antibiotics, birth control
6 pills, short-term medications, has any
7 applicability to blood pressure
8 medication?
9 A. I would have to look again.
10 I think this was a primary care
11 population. But I'm happy to look
12 through that data. I don't know if it
13 separated into different prescriptions.
14 Q. And you said that you had no
15 reason to assume that this -- you said
16 that you had no basis of knowledge about
17 the adherence of this class; is that
18 correct?
19 A. I have no information on
20 that.
21 Q. Did you ignore contrary
22 evidence?
23 MR. KUM: Objection.
24 Assumes facts not in evidence.

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1 THE WITNESS: I looked at
2 the general principle. I
3 didn't -- I have no -- I don't
4 know anything about this
5 population.
6 BY MS. GEMAN:
7 Q. Did you ask to see the
8 information about this population that's
9 available?
10 MR. KUM: Objection.
11 Outside the scope of her report.
12 THE WITNESS: I addressed
13 the medical monitoring and just
14 included adherence as one of the
15 concerns, if you're assigning
16 whatever dose of the impurity was
17 there.
18 BY MS. GEMAN:
19 Q. So did you ask to see
20 information about this population that's
21 available, if you're describing adherence
22 in your report at all?
23 A. I didn't --
24 MR. KUM: Same objection.

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1 Sorry.
2 THE WITNESS: I didn't know
3 it was available.
4 BY MS. GEMAN:
5 Q. Are you purporting to draw
6 any conclusions about adherence sitting
7 here now?
8 MR. KUM: Asked and
9 answered.
10 THE WITNESS: I describe the
11 concept.
12 BY MS. GEMAN:
13 Q. No. But are you purporting
14 to draw any conclusions whatsoever about
15 the adherence of this class?
16 A. I'm not.
17 MS. GEMAN: Thank you.
18 Okay.
19 Thank you for your time.
20 MR. KUM: Good. Thank you.
21 MR. KERNER: Thank you.
22 THE VIDEOGRAPHER: 4:21 p.m.
23 We are off the video record.
24 This concludes the video

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1 deposition of Dr. Ursina
2 Teitelbaum.
3 *****
4 (Excused.)
5 (Deposition concluded at
6 approximately 4:21 p.m.)
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1
2 CERTIFICATE
3
4
5 I HEREBY CERTIFY that the
6 witness was duly sworn by me and that the
7 deposition is a true record of the
8 testimony given by the witness.
9
10 It was requested before
11 completion of the deposition that the
12 witness, URSINA R. TEITELBAUM, M.D., have
13 the opportunity to read and sign the
14 deposition transcript.
15
16
17
18
19 MICHELLE L. GRAY,
20 A Registered Professional
21 Reporter, Certified Shorthand
22 Reporter, Certified Realtime
23 Reporter and Notary Public
24 Dated: March 14, 2022

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of this transcript does not apply to any
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INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it.

You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

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ACKNOWLEDGMENT OF DEPONENT

I, _____, do hereby certify that I have read the foregoing pages, 1 - 325, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

 URSINA R. TEITELBAUM, M.D. DATE

Subscribed and sworn to before me this _____ day of _____, 20____.

My commission expires: _____

 Notary Public

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LAWYER'S NOTES

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Exhibit 213

REDACTED

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF NEW JERSEY
3 CAMDEN VICINAGE

- - -

4 IN RE: VALSARTAN, : MDL NO. 2875
5 LOSARTAN, AND :
6 IRBESARTAN PRODUCTS : CIVIL NO.
7 LIABILITY LITIGATION : 19-2875
8 : (RBK/JS)

9 :
10 THIS DOCUMENT APPLIES : HON. ROBERT
11 TO ALL CASES : B. KUGLER

12 - CONFIDENTIAL INFORMATION -
13 SUBJECT TO PROTECTIVE ORDER

14 - - -

15 March 9, 2022

16 - - -

17 Videotaped remote deposition of
18 TIMOTHY A. ANDERSON, M.S., MBA, taken
19 pursuant to notice, was held via Zoom
20 Videoconference, beginning at 9:22 a.m.,
21 EST, on the above date, before Michelle
22 L. Gray, a Registered Professional
23 Reporter, Certified Shorthand Reporter,
24 Certified Realtime Reporter, and Notary
 Public.

- - -

25 GOLKOW LITIGATION SERVICES
26 877.370.3377 ph | 917.591.5672 fax
27 deps@golkow.com

<p style="text-align: right;">Page 2</p> <p>1 ZOOM APPEARANCES: 2 KANNER & WHITELEY, LLC 3 BY: DAVID J. STANOCH, ESQ. 4 CONLEE S. WHITELEY, ESQ. 5 701 Camp Street New Orleans, Louisiana 70130 (504) 524-5777 d.stanoch@kanner-law.com c.whiteley@kanner-law.com 6 Representing the Plaintiffs 7 GREENBERG TRAURIG, LLP 8 BY: STEVEN M. HARKINS, ESQ. 9 Terminus 200 3333 Piedmont Road NE Suite 2500 Atlanta, Georgia 30305 (678) 553-2312 harkinss@gtlaw.com 12 - and - 13 GREENBERG TRAURIG, LLP 14 BY: KENNETH DZIKOWSKI, ESQ. 15 500 Campus Drive Suite 400 Florham Park, New Jersey 07932 (973) 360-7900 Dzikowskik@gtlaw.com 17 - and - 18 GREENBERG TRAURIG, LLP 19 BY: BRIAN RUBENSTEIN, ESQ. 20 1717 Arch Street Philadelphia, Pennsylvania 19103 (215) 988-7800 rubensteinb@gtlaw.com 21 Representing the Defendants, Teva 22 Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., Actavis LLC, 23 and Actavis Pharma, Inc. 24</p>	<p style="text-align: right;">Page 4</p> <p>1 ZOOM APPEARANCES: (Cont'd.) 2 PIETRAGALLO GORDON ALFANO BOSICK & 3 RASPANTI, LLP BY: CHRISTOPHER S. WINKLER, ESQ. 4 One Oxford Centre, 38th Floor Pittsburgh, Pennsylvania 15219 5 (412) 263-1840 csw@pietragallo.com 6 Representing the Defendant, Mylan Pharmaceuticals, Inc. 7 8 ALSO PRESENT: 9 VIDEOTAPE TECHNICIAN: 10 Danny Ortega 11 12 13 14 15 16 17 18 19 20 21 22 23 24</p>
<p style="text-align: right;">Page 3</p> <p>1 ZOOM APPEARANCES: (Cont'd.) 2 WALSH PIZZI O'REILLY FALANGA LLP 3 BY: CHRISTINE I. GANNON, ESQ. 4 Three Gateway Center 100 Mulberry Street 15th Floor Newark, New Jersey 07102 (973) 757-1017 Cgannon@walsh.law 6 Representing the Defendants, Teva 7 Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., Actavis LLC, 8 and Actavis Pharma, Inc. 9 HINSHAW & CULBERTSON, LLP 10 BY: GEOFFREY M. COAN, ESQ. 11 53 State Street 27th Floor Boston, Massachusetts 02109 (617) 213-7047 Gcoan@hinshawlaw.com 13 Representing the Defendant, ScieGen Pharmaceuticals, Inc. 14 BARNES & THORNBURG, LLP 15 BY: MITCHELL CHARCHALIS, ESQ. 16 390 Madison Avenue 12th Floor New York, New York 10017 (646) 746-2000 Mcharchalis@btlaw.com 18 Representing CVS Pharmacy, Inc., and Rite Aid Corporation 19 20 21 22 23 24</p>	<p style="text-align: right;">Page 5</p> <p>1 - - - 2 I N D E X 3 - - - 4 5 Testimony of: 6 TIMOTHY A. ANDERSON, M.S., MBA 7 By Mr. Stanoch 12 8 By Mr. Harkins 412 9 10 11 12 - - - 13 E X H I B I T S 14 - - - 15 16 NO. DESCRIPTION PAGE 17 Anderson-1 Expert Report of 14 Timothy Anderson 18 1/12/22 19 Anderson-2 List of Materials 57 Considered 20 Anderson-3 Facts about the 108 21 Current Good Manufacturing Practices (cGMPs) 22 23 24</p>

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<p style="text-align: right;">Page 10</p> <p style="text-align: center;">- - - DEPOSITION SUPPORT INDEX - - -</p> <p>Direction to Witness Not to Answer PAGE LINE None.</p> <p>Request for Production of Documents PAGE LINE 64 9</p> <p>Stipulations PAGE LINE None.</p> <p>Questions Marked PAGE LINE None.</p>	<p style="text-align: right;">Page 12</p> <p>1 having been first duly sworn, was 2 examined and testified as follows: 3 4 EXAMINATION 5 6 BY MR. STANOCH: 7 Q. Good morning, Mr. Anderson. 8 A. Good morning. 9 Q. Could you just say your full 10 name for the record, sir? 11 A. Timothy A. Anderson. 12 Q. Thank you. Where are you 13 located today, sir, for this deposition? 14 A. I am located in Danbury, 15 Connecticut. 16 Q. And you're in a conference 17 room in a hotel right now for this remote 18 deposition, I believe? 19 A. Correct. 20 Q. And other than your counsel, 21 Mr. Harkins, is anybody else in the room 22 with you, sir? 23 A. No, sir. 24 Q. And you've been deposed</p>
<p style="text-align: right;">Page 11</p> <p style="text-align: center;">- - -</p> <p>THE VIDEOGRAPHER: We are now on the record. My name is Danny Ortega, and I'm the legal videographer for Golkow Litigation Services. Today's date is March 9th, 2022, and the time is 9:22 a.m. This video deposition is being held in the matter of Valsartan, Losartan, and Irbesartan Products Liability Litigation MDL, for the United States District Court, District of New Jersey. The deponent today is Timothy Anderson. All counsel will be noted on the stenographic record. The court reporter today is Michelle Gray and will now swear in the witness. - - - ... TIMOTHY A. ANDERSON, M.S., MBA,</p>	<p style="text-align: right;">Page 13</p> <p>1 before, I take it; is that right? 2 A. I have. 3 Q. So you understand the 4 process here. I'll be asking a series of 5 questions. You'll be providing answers. 6 Everything everyone says will be taken 7 down by the stenographer and on video. 8 You understand that, right? 9 A. I understand. 10 Q. Is it fair that I'll assume 11 you understand my question unless you 12 tell me otherwise, and I'll attempt to 13 rephrase? 14 A. That will be true, yes. 15 Q. Okay. And you know that you 16 should answer the question, unless your 17 counsel instructs you otherwise, right? 18 A. Correct. 19 Q. All right. If we need to 20 take a break later, just say so. If 21 there's a question pending, I'd ask that 22 you answer it. Is that fair? 23 A. That is fair. 24 Q. Okay. Any reason that you</p>

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1 cannot testify truthfully and accurately
2 today, sir?
3 A. No reason at all.
4 Q. Excellent. Let's get into
5 it.
6 Mr. Anderson, what's your
7 understanding of this litigation?
8 A. My understanding is that
9 John Quick has prepared a report, a
10 declaration that I was asked to review
11 and to rebut. And I was also asked to
12 review cGMP issues that were made by
13 auditors and inspectors.
14 Q. You've rendered opinions in
15 this case reflected in your report that
16 you submitted, correct?
17 A. Correct.
18 MR. STANOCH: I'm going to
19 mark that as Exhibit 1.
20 (Document marked for
21 identification as Exhibit
22 Anderson-1.)
23 BY MR. STANOCH:
24 Q. Let me know, sir, when you

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1 can access that on your screen.
2 MR. HARKINS: I'm going to
3 copy the exhibit share into the
4 chat if it hasn't already been
5 done so that he can open it up.
6 He also has a hard copy of the
7 report in front of him.
8 MR. STANOCH: That's fine.
9 And Mr. Harkins, do you want to
10 wait to get that set up with the
11 remote, or do you want me to start
12 asking questions? I'm fine
13 proceeding either way.
14 MR. HARKINS: Let's get it
15 set up. We had it on the other
16 computer. We switched. So we'll
17 quickly do that.
18 Do you see the chat
19 function?
20 THE WITNESS: I do.
21 MR. HARKINS: The link just
22 went up there.
23 BY MR. STANOCH:
24 Q. Just let me know when you

Page 16

1 can see that Exhibit 1, sir.
2 A. I'll let you know. I'm
3 trying to move it over to the other
4 screen. Okay. I'm there.
5 Q. Okay. Exhibit 1 is a copy
6 of your report in this litigation, right?
7 A. That's correct.
8 Q. And your report includes all
9 the opinions you're currently offering in
10 this matter, right?
11 A. Correct.
12 Q. And your opinions in your
13 report apply to all the plaintiffs in
14 this litigation, right?
15 A. They apply to Teva.
16 Q. You mentioned in Paragraph
17 19 class plaintiffs.
18 Do you see that?
19 A. Yeah.
20 Q. And what's your
21 understanding of who the class plaintiffs
22 are in this case?
23 A. I understand that there are
24 a class of plaintiffs and that there are

Page 17

1 a class of defendants in this case.
2 Q. Can you describe in more
3 detail the class of plaintiffs in this
4 case?
5 A. The class of plaintiffs are
6 those who are alleging injury. The class
7 of defendants are those who are accused.
8 Q. What injuries are the class
9 of plaintiffs alleging, to your
10 knowledge?
11 MR. HARKINS: Objection.
12 Requires a legal conclusion.
13 But you can answer if you do
14 understand.
15 THE WITNESS: I do not
16 understand all of the matters that
17 constitutes plaintiffs'
18 complaints.
19 BY MR. STANOCH:
20 Q. Well, what's the harm that
21 the class plaintiffs allege, to your
22 understanding?
23 A. They are -- they are
24 complaining of -- about valsartan.

Page 18

1 Q. In what respect?
2 A. In respect that they have
3 named, of all of these complaints
4 specifically that they are alleging. I
5 just know that they are alleging
6 complaints.
7 Q. You don't know the
8 complaints that the class plaintiffs are
9 alleging in this litigation against the
10 defendants?
11 A. Not in detail, no.
12 Q. Can you tell me anything
13 besides what you've told us already about
14 the complaints that the class plaintiffs
15 are alleging in this litigation against
16 the defendants?
17 A. All I know is that the class
18 plaintiffs are alleging harm.
19 Q. What kind of harm?
20 A. I do not have direct insight
21 into what specific class plaintiffs are
22 alleging.
23 Q. So you can't give me any
24 more detail about the purported harm that

Page 19

1 the class plaintiffs are alleging?
2 A. I cannot.
3 Q. Can you tell me who the
4 class plaintiffs are, either by name or
5 categorically?
6 A. I cannot.
7 Q. Can you tell me the forms of
8 relief that the class plaintiffs seek in
9 this litigation?
10 MR. HARKINS: Object to
11 form. Calls for a legal
12 conclusion.
13 THE WITNESS: I have no
14 legal opinion on that.
15 BY MR. STANOCH:
16 Q. I don't need a legal
17 opinion, sir, just your lay
18 understanding.
19 Can you tell me the forms of
20 relief that the class plaintiffs seek in
21 this litigation? And if you can't, you
22 can say you can't.
23 A. I can't.
24 Q. Can you tell me how many

Page 20

1 class plaintiffs there are?
2 A. I do not know.
3 Q. Can you tell me how many
4 states the class plaintiffs hail from?
5 A. I do not know.
6 Q. Can you tell me the time
7 period for which the class plaintiffs
8 alleged harm?
9 A. I don't know what exact time
10 frame the plaintiffs are alleging harm.
11 Q. Can you tell me any details
12 about the time frame for which the class
13 plaintiffs are alleging harm?
14 A. I cannot.
15 Q. Can you tell me anything
16 about the theories of liability the class
17 plaintiffs allege against the defendants
18 in this litigation?
19 MR. HARKINS: Form. Calls
20 for legal conclusion. Outside the
21 scope.
22 THE WITNESS: I have no
23 legal opinion to offer on this.
24 BY MR. STANOCH:

Page 21

1 Q. Putting aside any legal
2 opinion, which I don't want from you,
3 sir, can you tell me anything about the
4 theories of liability the class
5 plaintiffs allege against the defendants
6 in this litigation?
7 MR. HARKINS: Same
8 objection. Calls for a legal
9 conclusion.
10 THE WITNESS: My ability is
11 outside the scope of my report.
12 BY MR. STANOCH:
13 Q. Did you read the complaints
14 filed by the class plaintiffs in this
15 case, sir?
16 A. I read them once.
17 Q. And so -- and you did that
18 to familiarize yourself with the case,
19 I'm sure, right?
20 A. Generally correct.
21 Q. And can you identify for me
22 a single theory alleged in the class
23 complaints that you've read by the class
24 plaintiffs against the defendants?

Page 22

1 MR. HARKINS: Objection.
2 THE WITNESS: There is no
3 theory that I recall.
4 BY MR. STANOCH:
5 Q. Do your opinions in this
6 case depend on the number of class
7 members in a litigation?
8 A. No, it does not.
9 Q. Your opinions are the same
10 no matter how many class members there
11 may be, correct?
12 A. Correct.
13 Q. Do your opinions vary based
14 on which states a class plaintiff may
15 hail from?
16 A. No.
17 Q. Your opinions apply equally
18 no matter what particular state a
19 plaintiff may hail from, right?
20 A. Correct.
21 Q. Your opinions don't depend
22 on the specific theory of liability
23 alleged by any particular class
24 plaintiff, does it?

Page 23

1 A. I have no theory with
2 respect to liability.
3 Q. So your opinions don't
4 depend on the specific theory of
5 liability alleged by a particular class
6 plaintiff, correct?
7 A. Correct.
8 Q. How, if at all, can you tell
9 me that your opinions fit the theories of
10 liability alleged by the class plaintiffs
11 in this case?
12 MR. HARKINS: Object to
13 form. Vague. Calls for a legal
14 conclusion.
15 You can answer.
16 THE WITNESS: I'm not
17 opining on anything having to do
18 with liability or legal matters.
19 BY MR. STANOCH:
20 Q. So you cannot tell me how
21 your opinions fit the theories of
22 liability alleged by the class plaintiffs
23 in this case, correct?
24 MR. HARKINS: Object to

Page 24

1 form. Calls for legal conclusion,
2 scope. Asked and answered.
3 THE WITNESS: This is
4 outside the scope of my report.
5 BY MR. STANOCH:
6 Q. So the answer to that is,
7 correct, you cannot tell me how your
8 opinions fit the theories of liability
9 alleged by the class plaintiffs in this
10 case?
11 MR. HARKINS: Same
12 objection.
13 THE WITNESS: I stated that
14 it's outside the scope of my
15 report.
16 BY MR. STANOCH:
17 Q. Therefore, your opinions
18 have no bearing on fitting the theories
19 of liability alleged by the class
20 plaintiffs in this case?
21 MR. HARKINS: Object to
22 form. Calls for a legal
23 conclusion, misstates testimony.
24 Vague.

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1 THE WITNESS: Could you
2 repeat the question, please?
3 MR. STANOCH: Stand by.
4 THE WITNESS: Could you
5 repeat the question, please?
6 BY MR. STANOCH:
7 Q. Yes, sir. I was just
8 finding the question.
9 So earlier I asked you if
10 you can -- whether you could tell me how
11 your opinions fit the theories of
12 liability alleged by the class plaintiffs
13 in this case.
14 Objections.
15 And you said, I believe, "I
16 stated that's outside the scope of my
17 report."
18 Do you remember that?
19 A. I do remember that.
20 Q. So --
21 A. And --
22 Q. -- it's correct then that
23 you cannot tell me how your opinions fit
24 the theories of liability alleged by the

Page 26	Page 28
<p>1 class plaintiffs in this case?</p> <p>2 MR. HARKINS: Same</p> <p>3 objection.</p> <p>4 THE WITNESS: I have no</p> <p>5 opinion concerning liability.</p> <p>6 BY MR. STANOCH:</p> <p>7 Q. You cannot tell me how your</p> <p>8 opinions fit the theories alleged by the</p> <p>9 class plaintiffs in this case, can you?</p> <p>10 MR. HARKINS: Objection.</p> <p>11 Calls for a legal conclusion.</p> <p>12 You can answer.</p> <p>13 THE WITNESS: In that is a</p> <p>14 legal conclusion, I have no</p> <p>15 opinion.</p> <p>16 BY MR. STANOCH:</p> <p>17 Q. Again, I'm not asking for</p> <p>18 your legal conclusion ever, sir.</p> <p>19 Can you tell me how your</p> <p>20 opinions fit the theories alleged by the</p> <p>21 class plaintiffs in this case?</p> <p>22 MR. HARKINS: Same</p> <p>23 objection.</p> <p>24 THE WITNESS: I'm commenting</p>	<p>1 any of the particular theories alleged by</p> <p>2 class plaintiffs?</p> <p>3 MR. HARKINS: Object to</p> <p>4 form. Asked and answered. Calls</p> <p>5 for a legal conclusion.</p> <p>6 THE WITNESS: I am</p> <p>7 commenting on cGMP-related</p> <p>8 answers -- matters as they pertain</p> <p>9 to my rebuttal of John Quick's</p> <p>10 report.</p> <p>11 BY MR. STANOCH:</p> <p>12 Q. And that's the only thing</p> <p>13 that you're opining on, correct?</p> <p>14 A. Correct.</p> <p>15 Q. So you're not then opining</p> <p>16 on the application of any of your</p> <p>17 opinions to any particular theory alleged</p> <p>18 by plaintiffs, correct?</p> <p>19 MR. HARKINS: Form.</p> <p>20 THE WITNESS: I'm commenting</p> <p>21 only on cGMP-related matters.</p> <p>22 BY MR. STANOCH:</p> <p>23 Q. And are you applying your</p> <p>24 opinions of the cGMP matters to a</p>
Page 27	Page 29
<p>1 only on cGMP-related matters, not</p> <p>2 matters of liability.</p> <p>3 BY MR. STANOCH:</p> <p>4 Q. So how if at all do your</p> <p>5 theories fit -- strike that, sir.</p> <p>6 So how, if at all, do your</p> <p>7 opinions fit the theories alleged by the</p> <p>8 class plaintiffs in this case?</p> <p>9 MR. HARKINS: Object to</p> <p>10 form. Asked and answered.</p> <p>11 THE WITNESS: I'm commenting</p> <p>12 only on cGMP-related matters.</p> <p>13 BY MR. STANOCH:</p> <p>14 Q. None of your opinions have</p> <p>15 anything to do with the particular</p> <p>16 theories alleged by class plaintiffs</p> <p>17 then?</p> <p>18 MR. HARKINS: Object to</p> <p>19 form. Asked and answered.</p> <p>20 THE WITNESS: As I said, I'm</p> <p>21 commenting only on cGMP-related</p> <p>22 matters.</p> <p>23 BY MR. STANOCH:</p> <p>24 Q. Are you commenting then on</p>	<p>1 particular theory alleged by the class</p> <p>2 plaintiffs?</p> <p>3 MR. HARKINS: Object to</p> <p>4 form. Calls for a legal</p> <p>5 conclusion.</p> <p>6 THE WITNESS: I am</p> <p>7 commenting on cGMP-related</p> <p>8 matters.</p> <p>9 Theory is something which is</p> <p>10 vague.</p> <p>11 BY MR. STANOCH:</p> <p>12 Q. We talked earlier about the</p> <p>13 legal theories of harm alleged by class</p> <p>14 plaintiffs. You remember that, right?</p> <p>15 A. I recall you asking me about</p> <p>16 that.</p> <p>17 Q. Right. And I think you said</p> <p>18 that you're not familiar with the</p> <p>19 particular theories of harm alleged by</p> <p>20 the plaintiffs, correct?</p> <p>21 A. That's correct. Perhaps you</p> <p>22 have a theory that you'd like to bring</p> <p>23 up.</p> <p>24 Q. And I'm simply asking you</p>

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1 then, that the opinions you're offering
2 on cGMP are not applied to particular
3 theories of harm alleged by the class
4 plaintiffs, right?
5 MR. HARKINS: Form. Calls
6 for a legal conclusion.
7 THE WITNESS: Theory is a
8 very broad and general term, and I
9 can't answer that without knowing
10 what theory it is that you have a
11 question about.
12 BY MR. STANOCH:
13 Q. The theories of harm, sir.
14 A. Can you state what theory of
15 harm you're talking about?
16 Q. I asked you, sir, what were
17 class plaintiffs' theories of harm. And
18 you said that you don't know any of the
19 specific ones, correct?
20 A. Correct.
21 Q. So I'm asking you then, sir,
22 how do your opinions -- strike that.
23 So I'm asking you, sir,
24 whether it's true that because you don't

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1 know the class plaintiffs' theories of
2 harm, your opinions are not being applied
3 to a particular theory of harm alleged by
4 the class plaintiffs, right?
5 MR. HARKINS: Objection to
6 form. Asked and answered. Calls
7 for a legal conclusion.
8 THE WITNESS: Respectfully,
9 if there was a theory that you
10 have in mind, I can comment on it
11 in the context of cGMP-related
12 matters only.
13 BY MR. STANOCH:
14 Q. Got it. But sitting here
15 right now, you can't tell me a particular
16 theory of harm alleged by the class
17 plaintiffs, right?
18 MR. HARKINS: Object to
19 form. Asked and answered.
20 You can answer.
21 THE WITNESS: If you have a
22 theory of harm that is framed in
23 the context of cGMP issues, then I
24 can comment.

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1 Outside of that, your
2 request for me to comment on
3 theories which you have not
4 enunciated are ones I find are too
5 general for me to answer at this
6 time.
7 BY MR. STANOCH:
8 Q. Can you tell me a particular
9 claim alleged by any class plaintiffs?
10 MR. HARKINS: Object to
11 form. Asked and answered.
12 THE WITNESS: No, I cannot.
13 BY MR. STANOCH:
14 Q. Can you tell me then how
15 your opinions specifically apply to a
16 particular claim alleged by the class
17 plaintiffs?
18 MR. HARKINS: Object to
19 form. Asked and answered. Calls
20 for a legal conclusion.
21 THE WITNESS: I can comment
22 on cGMP-related matters as it
23 pertains to any comment that was
24 made in John Quick's report and on

Page 33

1 cGMP issues that were raised by
2 auditors and inspectors.
3 BY MR. STANOCH:
4 Q. Can you tell me how any
5 comments you make about Mr. Quick's
6 report or cGMP issues should fit any
7 particular claim alleged by the class
8 plaintiffs?
9 MR. HARKINS: Object to
10 form. Vague. Calls for a legal
11 conclusion.
12 THE WITNESS: I was asked to
13 evaluate John Quick's report and
14 to rebut John Quick's report and
15 provide opinions related to audits
16 and inspections made by FDA.
17 BY MR. STANOCH:
18 Q. Are you offering any
19 opinions, sir, on cGMP issues and how --
20 A. Yes --
21 Q. -- those issues fit to a
22 particular claim alleged by the class
23 plaintiffs?
24 MR. HARKINS: Object to

<p style="text-align: right;">Page 34</p> <p>1 form. Compound. Calls for a 2 legal conclusion. 3 THE WITNESS: I am 4 commenting on cGMP issues that 5 John Quick commented on and opined 6 upon and I was asked to rebut. 7 BY MR. STANOCH: 8 Q. And respectfully, sir -- 9 MR. STANOCH: Mr. Harkins, 10 as we've gone over a number of 11 times, per your side's request, 12 we're entitled to a yes or no 13 answer and then the witness may 14 explain. 15 So I'm going to ask it one 16 more time. And I'd ask that you 17 follow the Court's prior rulings. 18 And he can explain his answer 19 after he answers it yes or no. 20 BY MR. STANOCH: 21 Q. So, sir, can you tell me how 22 your opinions fit a particular claim 23 alleged by the class plaintiffs? 24 MR. HARKINS: Object to</p>	<p style="text-align: right;">Page 36</p> <p>1 Q. Did your opinions take into 2 account the specific legal claims alleged 3 by the class plaintiffs? 4 MR. HARKINS: Object to 5 form. Asked and answered. 6 THE WITNESS: Again, whether 7 they are legal claims, I do not 8 know. 9 To the extent that they are, 10 I'm only commenting on 11 cGMP-related matters. 12 BY MR. STANOCH: 13 Q. Were you asked by counsel to 14 make any assumptions for the purposes of 15 your report? 16 A. That question is a bit 17 general. Do you have a specific 18 assumption that you have in mind? 19 Q. I'm asking you, sir. I 20 don't know what you were asked to assume, 21 if anything. 22 Were you asked to assume any 23 fact in the preparation of your report? 24 MR. HARKINS: Just remind</p>
<p style="text-align: right;">Page 35</p> <p>1 form. Calls for a legal 2 conclusion. 3 To the extent that you were 4 asking for a yes or no answer as 5 to how his opinions fit the legal 6 theories that the parties are 7 discussing in this case, he is not 8 going to provide a yes or no 9 answer because he was not asked to 10 provide an opinion on how legally 11 any of his opinions fit the any of 12 the theories by either the 13 plaintiffs or the defendants in 14 this case. 15 You can answer. 16 THE WITNESS: As I said, I 17 was asked to rebut John Quick's 18 report and provide opinions on 19 inspections and audits that were 20 conducted by Teva and by health 21 authorities. 22 That is the extent of what I 23 was asked to do. 24 BY MR. STANOCH:</p>	<p style="text-align: right;">Page 37</p> <p>1 the witness not to discuss the 2 substance of any conversations 3 with counsel. 4 But subject to that, you can 5 answer. 6 THE WITNESS: There are no 7 assumptions that were sent to me, 8 if that's where you're going with 9 that. 10 BY MR. STANOCH: 11 Q. Were you asked to assume 12 that Teva's finished dose products 13 contained nitrosamines? 14 A. I was asked to review 15 documents that alleged that that is the 16 case. 17 Q. Are you assuming in 18 rendering your opinions in this case that 19 Teva's finished dose valsartan products 20 did contain nitrosamines? 21 A. There is evidence from 22 documentation to say such. 23 Q. Were you asked to assume 24 that nitrosamines became present in</p>

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1 Teva's finished dose products through API
2 purchased by ZHP or Mylan?
3 A. Documents were presented to
4 me which showed evidence thereof. There
5 were no assumptions that were made.
6 Q. Were you asked to assume
7 that at all times between 2012 to June of
8 2018, the valsartan API which Teva used
9 for its valsartan finished dose product
10 contained nitrosamines?
11 MR. HARKINS: Object to
12 form. Vague.
13 THE WITNESS: I was not
14 asked to assume anything.
15 Documentation was supplied to me
16 to provide evidence or lack
17 thereof that such a situation
18 existed.
19 BY MR. STANOCH:
20 Q. And what's your assessment
21 of whether such a situation existed?
22 A. The situation that I found
23 existed was that ZHP informed Teva of the
24 presence of NDMA in their drug substance,

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1 and they notified Teva of this fact. I
2 believe it was on June 6th of 2018.
3 Q. We'll come back to that,
4 sir.
5 Do you know whether Teva's
6 valsartan finished dose product between
7 2012 and June 2018 contained
8 nitrosamines?
9 A. Excuse me. May I revise
10 that last answer that I just gave you?
11 Q. Please.
12 A. Yes. More correctly, June
13 20th was the date on which Teva was
14 informed. As I'm recalling the document
15 that I read, it was on June 6th that ZHP
16 confirmed that they had nitrosamines in
17 their API, just for clarification.
18 Q. That's fine. I'll repeat
19 the question before the revision, which
20 was completely fine, Mr. Anderson. Feel
21 free to -- if you need to do that
22 throughout the day, let me know.
23 Do you know whether Teva's
24 valsartan finished dose product between

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1 2012 and June 2018 contained
2 nitrosamines?
3 A. I have no evidence to
4 suggest that.
5 Q. You don't know whether
6 Teva's valsartan finished dose products
7 contained nitrosamines?
8 A. You asked during a specific
9 time period. And I have no evidence that
10 Teva knew that there was NDMA present in
11 any of the drug product.
12 Q. Putting aside what Teva
13 knew. From your review of materials in
14 this case, did Teva's valsartan finished
15 dose product between 2012 and June 2018
16 contain nitrosamines?
17 A. Not as they were tested by
18 Teva. It wasn't evident.
19 Q. Regardless of whether Teva
20 tested them or not, do you know whether
21 Teva's finished dose product between 2012
22 and June of 2018 contained any
23 nitrosamines?
24 A. The API that was evaluated

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1 by ZHP in 2018 in terms of the
2 information request that FDA made of ZHP
3 showed that there were -- there was
4 evidence of NDMA in the API that ZHP
5 supplied lots for.
6 I don't know what lots Teva
7 had in their product, so it's hard for me
8 to say anything beyond what was revealed
9 in the ZHP response to FDA with regard to
10 specific lots of API.
11 Q. Is it fair to say that
12 you're not opining on which lots or
13 batches of valsartan finished dose
14 product made by Teva did or did not
15 contain nitrosamines?
16 A. I did not -- do not have
17 visibility to any direct connection
18 between a specific lot of API that was
19 manufactured by ZHP which had NDMA in it
20 and a lot of API that was utilized in a
21 Teva product.
22 Q. Right. But you did not
23 conduct any analysis in your report about
24 the levels of nitrosamines in any

<p>Page 42</p> <p>1 valsartan finished dose product, right?</p> <p>2 A. I do not.</p> <p>3 Q. You're not opining, right,</p> <p>4 about the levels of nitrosamines in any</p> <p>5 valsartan finished dose product, correct?</p> <p>6 A. I am not.</p> <p>7 Q. You're not opining about</p> <p>8 whether or not a particular valsartan</p> <p>9 finished dose product did or did not</p> <p>10 contain nitrosamines, right?</p> <p>11 A. Correct.</p> <p>12 Q. You're not opining about the</p> <p>13 levels of nitrosamines in any valsartan</p> <p>14 API, correct?</p> <p>15 A. I'm not opining about the</p> <p>16 specific levels, not at all.</p> <p>17 Q. You're not opining on</p> <p>18 whether a particular batch of valsartan</p> <p>19 API did or did not contain nitrosamines,</p> <p>20 right?</p> <p>21 A. I am not opining. I have</p> <p>22 reviewed documents supplied by ZHP</p> <p>23 specifically where they revealed that</p> <p>24 they had NDMA present in lots of API</p>	<p>Page 44</p> <p>1 with dimethylformamide, DMF.</p> <p>2 Q. And we can agree for</p> <p>3 purposes of today that NDMA, that's a</p> <p>4 type of nitrosamine, right?</p> <p>5 A. It is.</p> <p>6 Q. We can agree for purposes of</p> <p>7 today that NDEA is a type of nitrosamine,</p> <p>8 correct?</p> <p>9 A. Correct.</p> <p>10 Q. And is it fair then that</p> <p>11 when we refer to nitrosamines throughout</p> <p>12 the day, that would include both NDMA and</p> <p>13 NDEA, fair?</p> <p>14 A. In the proper context, yes.</p> <p>15 Q. Sure.</p> <p>16 If you ever need to ever</p> <p>17 split it out, feel free to do so. Is</p> <p>18 that okay?</p> <p>19 A. That's okay.</p> <p>20 Q. Do you agree that</p> <p>21 nitrosamines are genotoxic?</p> <p>22 A. It is alleged that they are</p> <p>23 genotoxic. And it is suspected that they</p> <p>24 are genotoxic. There have been studies</p>
<p>Page 43</p> <p>1 which were featured as part of that</p> <p>2 response to FDA.</p> <p>3 But I have no connection to</p> <p>4 any one of those lots of API, as they</p> <p>5 were -- with respect to Teva products.</p> <p>6 Q. That's fair. You're not</p> <p>7 conducting any batch or lot analysis of</p> <p>8 valsartan API for nitrosamine levels,</p> <p>9 fair?</p> <p>10 A. That is correct.</p> <p>11 Q. And we've been talking about</p> <p>12 nitrosamines a little bit. What's your</p> <p>13 understanding of a nitrosamine, sir?</p> <p>14 A. Nitrosamines is a an</p> <p>15 artifact of production, a process</p> <p>16 impurity specifically, which arises and</p> <p>17 was found to arise in a detailed sense as</p> <p>18 described by ZHP, where, if I recall,</p> <p>19 that there was a substitution of</p> <p>20 triethylamine hydrochlorothiazide with</p> <p>21 zinc chloride as a catalyst.</p> <p>22 And I believe that there was</p> <p>23 a -- either an admission or substitution</p> <p>24 of methyl tertiary butyl either, MTBE</p>	<p>Page 45</p> <p>1 that have been done, as I understand it,</p> <p>2 preclinically to suggest that they are</p> <p>3 genotoxic.</p> <p>4 Q. Did you have any</p> <p>5 professional familiarity with</p> <p>6 nitrosamines prior to your engagement in</p> <p>7 this case?</p> <p>8 A. I did not.</p> <p>9 Q. Do you agree that</p> <p>10 nitrosamines are probable human</p> <p>11 carcinogens?</p> <p>12 MR. HARKINS: Object to</p> <p>13 form. Scope.</p> <p>14 THE WITNESS: They have been</p> <p>15 characterized as such by FDA.</p> <p>16 BY MR. STANOCH:</p> <p>17 Q. Do you agree that</p> <p>18 nitrosamines are not an active ingredient</p> <p>19 in any FDA-approved drug?</p> <p>20 A. I agree, to my knowledge,</p> <p>21 that that is true.</p> <p>22 Q. Do you agree that</p> <p>23 nitrosamines are part of the cohort of</p> <p>24 concern under ICH M7 guidance?</p>

<p style="text-align: right;">Page 46</p> <p>1 A. I'm aware of that, yes.</p> <p>2 Q. Would you agree that the</p> <p>3 presence of nitrosamines, even at trace</p> <p>4 levels, could be considered unacceptable</p> <p>5 because these impurities are potential</p> <p>6 human carcinogens?</p> <p>7 MR. HARKINS: Object to</p> <p>8 form. Vague. Scope.</p> <p>9 THE WITNESS: There's a</p> <p>10 point in time that they were</p> <p>11 deemed to be unsuitable and</p> <p>12 unacceptable according to a</p> <p>13 registry standard that FDA</p> <p>14 established for them.</p> <p>15 BY MR. STANOCH:</p> <p>16 Q. Do you recall what that</p> <p>17 specific point in time was?</p> <p>18 A. That point in time there</p> <p>19 were initial limits that were set by FDA.</p> <p>20 I believe it was in December of 2018.</p> <p>21 Q. Okay. Prior to December of</p> <p>22 2018, were there any limits set by the</p> <p>23 FDA for how much nitrosamine could be in</p> <p>24 any drug?</p>	<p style="text-align: right;">Page 48</p> <p>1 Pharmaceuticals, Arrow Pharmaceuticals,</p> <p>2 which over time became Teva companies.</p> <p>3 So they are affiliates in</p> <p>4 that sense that they were not part of the</p> <p>5 original Teva, but are entities,</p> <p>6 operating entities, that predate Teva's</p> <p>7 acquisition of them. Hence, I refer to</p> <p>8 them as affiliates.</p> <p>9 Q. Got it. So it's fair to say</p> <p>10 Watson, Actavis, Arrow would be</p> <p>11 predecessor entities that were acquired</p> <p>12 or became part of Teva at a certain</p> <p>13 point?</p> <p>14 A. Correct.</p> <p>15 Q. Do you know when any of</p> <p>16 those entities became a part of Teva?</p> <p>17 A. I don't have the exact</p> <p>18 recollection of specific dates. I</p> <p>19 believe they are in my report. And I</p> <p>20 don't have immediate recollection of what</p> <p>21 those are.</p> <p>22 If you would like me to go</p> <p>23 through my report and find that paragraph</p> <p>24 where I detailed it, I would be happy to</p>
<p style="text-align: right;">Page 47</p> <p>1 A. There were none.</p> <p>2 Q. And were you aware of any</p> <p>3 limits that allowed any amount of NDMA or</p> <p>4 NDEA in a drug set by any regulatory</p> <p>5 agency or professional body?</p> <p>6 A. None of which I am aware.</p> <p>7 Q. In Paragraph 19 of your</p> <p>8 report, sir -- tell me when you're there.</p> <p>9 A. I'm here.</p> <p>10 Q. You say that counsel for</p> <p>11 Teva Pharmaceuticals USA, Inc., and its</p> <p>12 affiliates, collectively Teva, asked you</p> <p>13 to review and respond to certain issues</p> <p>14 as you set forth in this paragraph,</p> <p>15 right?</p> <p>16 A. Correct, as I've stated.</p> <p>17 Q. Who are the affiliates that</p> <p>18 you're including in your definition of</p> <p>19 Teva?</p> <p>20 A. Teva company is comprised of</p> <p>21 a series of -- we'll call them predicate</p> <p>22 companies' names, of which that come to</p> <p>23 mind are Watson Pharmaceuticals,</p> <p>24 Actavis -- excuse me -- yes, Actavis</p>	<p style="text-align: right;">Page 49</p> <p>1 try and locate it and read it back to</p> <p>2 you.</p> <p>3 Q. I appreciate that. But we</p> <p>4 don't need to do that quite yet. Just so</p> <p>5 we are on the same page throughout the</p> <p>6 day.</p> <p>7 Is it your understanding</p> <p>8 that Watson was acquired by Actavis, and</p> <p>9 then Actavis was acquired by Teva at some</p> <p>10 point?</p> <p>11 A. I believe that was the</p> <p>12 sequence.</p> <p>13 Q. I think Arrow, that was also</p> <p>14 a facility that was -- or company under</p> <p>15 Actavis, and then Actavis came part of</p> <p>16 Teva, right?</p> <p>17 A. That could be true. I don't</p> <p>18 have immediate recollection to know. But</p> <p>19 I'll accept your statement.</p> <p>20 Q. All right. And so</p> <p>21 throughout the day, we may refer to Teva.</p> <p>22 And can we understand that Teva would</p> <p>23 mean both sort of legacy Teva, as well as</p> <p>24 entities which it acquired at some point</p>

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1 for purposes of your report?

2 A. Yes.

3 Q. Right. So for example, we

4 can say, you know, Teva sourced valsartan

5 API from two suppliers, ZHP and Mylan,

6 right?

7 A. Yes.

8 Q. And we understand though,

9 that it might have been Actavis initially

10 sourcing that API from ZHP, but then it

11 continued doing that once it was acquired

12 at some point by Teva, right?

13 A. Agreed, yeah.

14 Q. Great. And you agree that

15 Actavis was sourcing valsartan API from

16 ZHP, correct?

17 A. Yes. That's correct.

18 Q. And then it continued to do

19 so once it was acquired by Teva, right?

20 A. Correct.

21 Q. And Teva was also sourcing

22 API from Mylan for manufacture into

23 finished dose valsartan at its Jerusalem

24 facility, right?

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1 A. That is my understanding,

2 yes.

3 Q. Do you know approximately

4 when Actavis was acquired by Teva?

5 A. I can look up that exact

6 date, I believe that I have in my report.

7 I have an idea of what that date is. But

8 if you'll allow me the freedom to guess

9 on this --

10 MR. HARKINS: Don't guess,

11 please.

12 THE WITNESS: I've been

13 advised not to guess.

14 Would you like me to find it

15 in my report?

16 BY MR. STANOCH:

17 Q. Sure.

18 I'm just making sure that we

19 have a timeline as we go through the day,

20 sir. And if later, you have to correct

21 it.

22 When do you think Teva

23 acquired Actavis? Even a year is fine.

24 A. Again, yeah, I don't want to

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1 guess. What I will say is that it is

2 sometime between 2012 and 2018.

3 Q. That's good enough. I

4 appreciate that, sir. We can agree, you

5 know, for now, that sometime during the

6 2012 and 2018 time period, Actavis was

7 acquired by Teva, right?

8 A. Agreed.

9 Q. Great. And if later it

10 becomes particularly pertinent about the

11 timing on it, feel free to look it up

12 your report and let me know that you need

13 to.

14 Is that okay?

15 A. I will.

16 Q. Great. In Paragraph 20 of

17 your report, sir, you talk about some of

18 the regulatory inspections that were

19 pertinent to your opinions here?

20 A. Correct.

21 Q. That includes FDA inspection

22 of Teva facilities, right?

23 A. It does.

24 MR. HARKINS: Are you

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1 hearing an echo?

2 MR. STANOCH: Yes.

3 MR. HARKINS: Can we go off

4 the record for one second.

5 THE VIDEOGRAPHER: The time

6 right now is 10:01 a.m. We are

7 off the record.

8 (Short break.)

9 THE VIDEOGRAPHER: The time

10 right now is 10:04 a.m. We're

11 back on the record.

12 BY MR. STANOCH:

13 Q. Mr. Anderson, welcome back.

14 We were looking at Paragraph 20 of your

15 report. Do you remember that?

16 A. I see the paragraph, yes.

17 It's in front of me.

18 Q. And we were saying how you

19 looked at FDA inspections of Teva

20 facilities, right?

21 A. Yes, that is correct. I

22 believe that's in Paragraph 21.

23 Q. And that would be FDA

24 inspections of the two Teva facilities

<p style="text-align: right;">Page 54</p> <p>1 that manufactured valsartan for the U.S. 2 market, the Jerusalem facility, and I'll 3 call it the Malta facility? 4 A. Correct. 5 Q. And you also looked at the 6 Malta authority's inspection of, I 7 assume, the Teva Malta facility? 8 A. Correct. 9 Q. Did you look at any Israeli 10 inspections of the Teva Jerusalem 11 facility? 12 A. I did. 13 Q. You did. Where do you say 14 that? 15 A. There is evidence thereof in 16 the appendix and later on in the report 17 of -- if it is not mentioned in this 18 paragraph, that is just something that I 19 did not happen to include, but it is 20 something which is very much part of my 21 report. 22 Q. So you're saying that you 23 did look at Israeli authority inspection 24 documents for the Teva Jerusalem</p>	<p style="text-align: right;">Page 56</p> <p>1 look at any Israeli government authority 2 inspections of Teva's Jerusalem facility? 3 A. I did not. 4 Q. And you mentioned the 5 materials considered. I want to ask you 6 a few questions about that. 7 You have an appendix on 8 exhibit to your report, Exhibit B, 9 correct? 10 A. Yes, I do. 11 Q. And this is the list of 12 materials considered; is that right? 13 A. That is correct. 14 Q. And I also understand, and I 15 can put it in front of you, there's a 16 slightly revised version of this to 17 update that you may have read a few 18 additional deposition transcripts or 19 parties' experts who might have been 20 deposited since you issued your report, 21 right? 22 A. That is correct. 23 Q. I can put it in front of 24 you. But other than the other deposition</p>
<p style="text-align: right;">Page 55</p> <p>1 facility? 2 A. I did. 3 Q. And I don't see it here in 4 your Section 2. 5 Where might that appear in 6 your report? 7 A. Okay. One moment, please. 8 I do make reference to the host of 9 inspections which were -- which had taken 10 place. I'm looking at Page 43 of my 11 report, Section 3, which is entitled "FDA 12 Inspection of Teva Israeli, October 13th 13 through 17 of 2013." Following on Page 14 44, with "FDA Inspection of Teva Israeli 15 June 16th to 22, 2015." 16 And of course the details of 17 the observations that were made by FDA at 18 Teva Israeli are noted in the appendix. 19 Q. I certainly agree that you 20 opine in your report about FDA 21 inspections of Teva Israel, including 22 those set forth in Paragraphs 172 to 176 23 of your report. 24 My question was, did you</p>	<p style="text-align: right;">Page 57</p> <p>1 transcripts that you might have read 2 between the issuance of your report and 3 now, were there any other differences 4 that you recall between your original 5 materials considered list and the more 6 recent material considered list? 7 A. Well, to be complete, I 8 received expert reports from defendants 9 that were supplied to me as well as 10 expert reports from plaintiffs' side. So 11 that's in addition to reviewing 12 deposition transcripts, to be very clear. 13 So that is how this 14 materials considered has been 15 supplemented. 16 Q. Perfect. And just for the 17 record I'm going to mark as Exhibit 2 18 your updated materials considered list so 19 if we need it throughout the day, it will 20 be there. 21 I don't think we need to 22 belabor it at this point. 23 (Document marked for 24 identification as Exhibit</p>

<p style="text-align: right;">Page 58</p> <p>1 Anderson-2.)</p> <p>2 BY MR. STANOCH:</p> <p>3 Q. So going back to the</p> <p>4 materials considered, are all of these</p> <p>5 documents and other materials listed on</p> <p>6 it, your Exhibit B, are you relying on</p> <p>7 all of this material to render your</p> <p>8 opinions in your report?</p> <p>9 A. No, I am not. And</p> <p>10 particularly the new reports and</p> <p>11 deposition transcripts which were not in</p> <p>12 existence prior to January 12th when I</p> <p>13 submitted my completed report, these were</p> <p>14 not part of anything that informed me</p> <p>15 during the writing of my report because</p> <p>16 they did not exist at that time.</p> <p>17 Q. That's fair. But everything</p> <p>18 else you list, these are all documents</p> <p>19 that you're relying onto render your</p> <p>20 opinions?</p> <p>21 A. I have -- this is a list of</p> <p>22 materials considered.</p> <p>23 Not every document here is</p> <p>24 one with which I elect to become</p>	<p style="text-align: right;">Page 60</p> <p>1 sounds like your Exhibit B, materials</p> <p>2 considered, is sort of the universe of</p> <p>3 what was made available to you, and then</p> <p>4 ultimately what you relied upon is some</p> <p>5 subset of that universe?</p> <p>6 A. Relied upon to rebut John</p> <p>7 Quick's report, that is correct.</p> <p>8 Q. Right. So how can I tell,</p> <p>9 looking at your Exhibit B, materials</p> <p>10 considered, what materials you're relying</p> <p>11 on rendering your opinions in this case,</p> <p>12 and which were simply materials made</p> <p>13 available to you that you might have</p> <p>14 looked at briefly but you're not really</p> <p>15 relying on to render your opinions?</p> <p>16 A. We would actually have to go</p> <p>17 down a list one by one there and then</p> <p>18 make a comparison to what specific</p> <p>19 citation was made in John Quick's report.</p> <p>20 If there is a citation in John Quick's</p> <p>21 report that also appears on this list of</p> <p>22 materials considered, one may say I was</p> <p>23 relying on that very specific document to</p> <p>24 form my opinion.</p>
<p style="text-align: right;">Page 59</p> <p>1 intimately familiar, although I may have</p> <p>2 read it.</p> <p>3 The documents which are in</p> <p>4 here should line up with those that were</p> <p>5 ones that John Quick had referenced. And</p> <p>6 this is really where I started my</p> <p>7 document review, was directly in line</p> <p>8 with documentation that John Quick has</p> <p>9 supplied for his report.</p> <p>10 And so all of that</p> <p>11 documentation resides in this list of</p> <p>12 materials considered. So I would have</p> <p>13 made the point to review those references</p> <p>14 that John Quick made specifically.</p> <p>15 However, there are other</p> <p>16 documents in here that, while they were</p> <p>17 made available to me, I may have simply</p> <p>18 had a look at them and decided at that</p> <p>19 point that they were not necessary for me</p> <p>20 to actually cite in my report.</p> <p>21 But in the manner of full</p> <p>22 disclosure, these are the documents that</p> <p>23 I became acquainted with to some degree.</p> <p>24 Q. I appreciate that. So it</p>	<p style="text-align: right;">Page 61</p> <p>1 Q. Have you undertaken that</p> <p>2 exercise of -- that you just described,</p> <p>3 making the comparison?</p> <p>4 A. I do that in my report.</p> <p>5 In fact, there are a number</p> <p>6 of occasions where I quote Mr. Quick</p> <p>7 directly and also comment upon the</p> <p>8 citation that he has provided.</p> <p>9 Q. So sitting here today, is</p> <p>10 there any way you can tell me, in your</p> <p>11 materials considered, which materials are</p> <p>12 ones that you are relying on in rendering</p> <p>13 your opinions, or would you have to go</p> <p>14 through this comparison exercise, as you</p> <p>15 described it?</p> <p>16 A. I think the comparison</p> <p>17 exercise would be the most accurate way</p> <p>18 to go about doing that.</p> <p>19 Q. Have you undertaken that</p> <p>20 comparison exercise prior to today?</p> <p>21 A. I made it a point to provide</p> <p>22 to counsel the list of materials that I</p> <p>23 used to prepare my report that were those</p> <p>24 which John Quick relied upon, and other</p>

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1 materials that I requested that I wanted
2 to see to provide more color to my
3 understanding of an issue.
4 Q. I don't think that list
5 was -- go ahead.
6 A. Yeah. Let me give you a for
7 instance. When John Quick says that he
8 did not review any of the details of the
9 Mylan inspection that Teva provided, by
10 contrast, I requested that document to
11 review myself, to become acquainted with
12 what the issues were that Teva inspectors
13 found at Mylan.
14 It was really the same with
15 respect to any of these other audit
16 reports that the outcomes of --
17 observations of which are contained in my
18 exhibit.
19 So those were not ones that
20 John Quick appeared to have any knowledge
21 of, as I read his -- as I read his
22 transcript, but in fact, I made it a
23 point to obtain myself to inform me.
24 Q. Short of us engaging in the

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1 comparison exercise that you've described
2 and going by one by one through all the
3 documents and other materials in your
4 Exhibit B right now, is there any other
5 way that you'd be able to tell me which
6 materials considered you actually relied
7 upon in rendering your opinions in your
8 report?
9 A. If I footnote them in my
10 report they will be references that
11 appeared in John Quick's report, pretty
12 closely one to one, since I'm rebutting
13 point for point. And I'm also taking
14 into consideration what documentation he
15 used to support his opinion.
16 So if you read my report and
17 read the footnotes in there, those are
18 what comprise the core of my opinion and
19 what documents were very specific to
20 informing my opinion.
21 Q. So is it fair to say that if
22 a material is mentioned in the body or
23 footnotes of your report, it was
24 something that you relied upon for your

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1 opinions, and that would give me the full
2 list of the reliance materials?
3 MR. HARKINS: Object to
4 form. Compound.
5 THE WITNESS: Well,
6 materials that I reference in my
7 report are those which support my
8 opinion.
9 MR. STANOCH: Right. And
10 well, first before I forget, I'm
11 just going to put on the record,
12 you know, that we weren't provided
13 any list of the reliance materials
14 versus materials considered, as
15 Mr. Anderson mentioned a few
16 moments ago. So we're going to
17 request that.
18 BY MR. STANOCH:
19 Q. And so Mr. Anderson, let me
20 just take an example.
21 So go to -- if I just go to
22 your materials considered, there's a
23 number of certificates of analysis and
24 certificates of conformance listed,

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1 right?
2 A. Yeah.
3 Q. And these were made
4 available to you, I take it, correct?
5 A. Correct.
6 Q. Now, how do I know which, if
7 any, of these certificates of analysis or
8 conformance you're relying on to render
9 the opinions reflected in your report?
10 A. If I refer you to --
11 certificate of conformance --
12 (Audio interference.)
13 BY MR. STANOCH:
14 Q. We did not get your answer
15 from audio interference on your end. So
16 just for the record, I'm going to re-ask
17 my question, sir, and then you can begin
18 again. Okay?
19 A. That's fair enough. Thank
20 you.
21 Q. How do I know which, if any,
22 of these certificates of analysis or
23 conformance you're relying on to render
24 the opinions reflected in your report?

<p style="text-align: right;">Page 66</p> <p>1 A. You will note it on the 2 materials considered. There is also a 3 Bates number that corresponds to that 4 certificate of conformance. And if I 5 referred to anything having to do with 6 that specific certificate of conformance, 7 it would be footnoted in my report 8 according to the Bates number that 9 corresponds to it.</p> <p>10 Q. I see. So unless the Bates 11 number or other unique identifier is 12 footnoted or explicitly noted in the body 13 of your report, that material is not one 14 you're relying on to render your 15 opinions?</p> <p>16 A. That is correct.</p> <p>17 Q. Let's flip back to the body 18 of your report around Page 6 and 7. And 19 tell me when you're there, sir?</p> <p>20 A. I'm there.</p> <p>21 Q. And in Paragraph 22, you're 22 summarizing your opinion about whether 23 Teva had evidence to suggest that NDMA or 24 NDEA would be present in the API</p>	<p style="text-align: right;">Page 68</p> <p>1 I know what certificates of analysis 2 you're relying on to render your opinion 3 as to whether Teva had evidence or not 4 from certificates of analysis?</p> <p>5 A. I cannot tell you what is on 6 each of the specific certificates of 7 analysis that are listed in the list of 8 materials considered.</p> <p>9 There were certificates of 10 analysis that were available for review, 11 let's say, in the ANDAs.</p> <p>12 There were -- that I recall 13 being familiar with. They could be among 14 those certificates of conformance -- 15 conformance or analysis, as they're 16 described, that I reviewed in the course 17 of reviewing documentation generally for 18 this case.</p> <p>19 Q. Well, you told us moments 20 ago that unless it's specifically cited 21 in the body of your report, it's not one 22 you're relying on for your opinions, 23 right?</p> <p>24 A. That is correct.</p>
<p style="text-align: right;">Page 67</p> <p>1 purchased from ZHP or Mylan, right?</p> <p>2 A. Correct.</p> <p>3 Q. And what types of evidence 4 are you referring to in that instance?</p> <p>5 A. Evidence that would have 6 appeared on certificates of analysis.</p> <p>7 Q. Anything else?</p> <p>8 A. Evidence that would have 9 arisen as a consequence of an observation 10 made either by an auditor from Teva or an 11 inspector from FDA.</p> <p>12 Q. Anything else?</p> <p>13 A. Nothing else.</p> <p>14 Q. And which certificates of 15 analysis are you referring to 16 specifically?</p> <p>17 A. There would be certificates 18 of analysis that pertained to Teva 19 product that would be issued for API, as 20 well as for completed and finished drug 21 product.</p> <p>22 Q. As we talked about some 23 moments ago, there's no footnote or Bates 24 citation here in Paragraph 22. So how do</p>	<p style="text-align: right;">Page 69</p> <p>1 Q. So now I'm asking you, where 2 in your report at Paragraph 22 or 3 otherwise, are you specifically citing 4 any certificate of analysis that you just 5 told us is the basis for your opinion in 6 Paragraph 22, at least in part?</p> <p>7 A. I'm saying that I reviewed 8 certificates of analysis. And those 9 certificates of analysis that I reviewed 10 reported no evidence of the presence of 11 NDMA or NDEA in any of them.</p> <p>12 Q. Which certificates did you 13 review?</p> <p>14 A. I reviewed some certificates 15 for API and some certificates for drug 16 product.</p> <p>17 Q. Which ones?</p> <p>18 A. I cannot tell you at this 19 time, which ones that I reviewed 20 specifically --</p> <p>21 Q. You --</p> <p>22 A. -- apart from the ones -- 23 apart from the ones that are listed in 24 the materials considered.</p>

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1 They may have been
2 considered, and I may have, upon viewing
3 them, made a mental note that no, I don't
4 have -- see any NDMA or NDEA evidence on
5 any certificates of analysis.
6 Q. You may have.
7 Did you do that? Yes or no?
8 A. I did. I looked at all of
9 the certificates of conformance that are
10 listed there. But I had no specific
11 comments to make on any of them in that I
12 did not find any NDMA or NDEA mentioned
13 on any of the certificates of analysis.
14 Q. So there's nothing in the
15 body of your report, though, that tells
16 me which specific Bates number I should
17 look at for the certificates of analysis
18 or conformance that you're claiming you
19 reviewed for your opinion that Teva did
20 not have evidence to suggest NDMA or NDEA
21 would be present.
22 MR. HARKINS: Object to
23 form. Asked and answered.
24 THE WITNESS: I do not make

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1 a direct connection between
2 certificates of analysis. They're
3 in the materials considered, so
4 they do appear in the materials
5 considered. I don't cite them
6 here.
7 BY MR. STANOCH:
8 Q. So how -- looking at your
9 report, how am I to know whether or not
10 any material listed in your materials
11 considered is actually something you
12 relied upon for an opinion as written in
13 your report, or if it was just something
14 that you looked at but you're not
15 specifically relying on it?
16 MR. HARKINS: Object to
17 form.
18 He just explained exactly
19 how you should do that for this
20 material.
21 THE WITNESS: Again, the
22 certificates of conformance or
23 certificates of analysis, as they
24 are also often referred to, that

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1 are listed here are ones which I
2 considered.
3 And in that they did not
4 contain NDMA or NDEA in any kind
5 of report on there, it was not
6 necessary for me to say anything
7 more than what I've said here
8 about that matter, because I found
9 no records of NDMA or NDEA that
10 were in those certificates of
11 conformance.
12 BY MR. STANOCH:
13 Q. How can I replicate your
14 analysis if I don't know what specific
15 documents you're relying on for specific
16 opinions in the paragraphs of your
17 report?
18 MR. HARKINS: Object to
19 form. Asked and answered.
20 THE WITNESS: Once again, if
21 there is documents that I have
22 cited in this report or has been
23 referenced by Mr. Quick and I've
24 discussed it as a matter of that,

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1 certainly it has been footnoted
2 here.
3 And again as I say, I was
4 furnished a number of documents
5 here which, while I reviewed them,
6 I did not find -- feel it was
7 necessary to have to go through
8 document by document by document
9 here to say that I didn't see any
10 NDMA on certificate analysis
11 Number 1, Number 2, Number 3,
12 Number 4, Number 5.
13 I didn't find that to be
14 necessary for me to do, but merely
15 to state that as I've done so
16 here.
17 BY MR. STANOCH:
18 Q. We can agree that Paragraph
19 22 doesn't mention certificates of any
20 form, right?
21 A. Correct.
22 Q. And you have no footnote as
23 any source for Paragraph 22, correct?
24 A. That's correct.

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1 Q. All right. And you told us
2 that if it wasn't specifically cited in
3 the body or a footnote in your report,
4 you're not relying on it, correct?
5 MR. HARKINS: Object to
6 form.
7 He just explained how he was
8 relying on the certificates of
9 conformance for the paragraph
10 you're talking about. Misstates
11 his testimony.
12 THE WITNESS: Again, I
13 believe I've discussed how I
14 incorporate here and account for
15 on the list of materials that I
16 considered, which materials those
17 were.
18 But you're correct, there is
19 no citation for certificates of
20 analysis in Paragraph 22.
21 BY MR. STANOCH:
22 Q. And the only way that I
23 would be able to determine which
24 documents you relied on for, say, the

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1 opinion in paragraph 22, would be to go
2 document by document with you through
3 your materials considered?
4 A. That's correct. And also
5 you may consult my evaluation of the
6 auditors and inspectors reports which
7 reside in the exhibit that's provided for
8 them.
9 Q. And you also made a list of
10 the documents that you relied on, which
11 was a subset of the materials considered,
12 which you gave to counsel, right?
13 MR. HARKINS: Object to
14 form. Misstates the testimony.
15 THE WITNESS: I did not make
16 a separate list which involved
17 only documents that were
18 referenced by John Quick.
19 BY MR. STANOCH:
20 Q. Did you make a separate list
21 of the materials that you relied on to
22 render the opinions in your report, which
23 was a subset of the materials considered?
24 MR. HARKINS: Object to

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1 form. Misstates his testimony.
2 THE WITNESS: And how you
3 clarified that correctly was to
4 say that these were documents that
5 Mr. Quick supplied in his report,
6 and I confirmed that in fact that
7 is -- that's the documents that I
8 used to rebut John Quick's
9 statements on the basis of
10 references that he made to such
11 documents.
12 So you characterized that as
13 a subset of documents, and you're
14 free to do so. But there was no
15 separation of documentation in
16 that way that I made in this
17 report that way.
18 BY MR. STANOCH:
19 Q. Then the next paragraph, you
20 talk about Teva's quality control
21 systems?
22 A. Correct.
23 Q. And you make reference to
24 Teva quality system, specifically the

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1 standard operating procedure, SOP CORP --
2 CORP-0001.
3 A. Correct.
4 Q. And that is -- strike that.
5 That SOP is what?
6 A. That SOP is the -- we'll
7 call it an anchor SOP from which other
8 SOPs proceed.
9 It is a statement of what
10 the quality system is that Teva is
11 expected to uphold.
12 And from that SOP, there are
13 other SOPs that proceed to cover specific
14 areas that comprise the quality system.
15 Q. And SOP CORP-0001, that's a
16 Teva standard operating procedure, right?
17 A. Yes. It is a foundational
18 SOP.
19 Q. SOP CORP-0001 would not have
20 applied to Actavis prior to Teva's
21 acquisition of Actavis, correct?
22 A. Not prior to Teva's
23 acquisition of Actavis. I understand
24 that CORP-0001 as an SOP is something

<p style="text-align: right;">Page 78</p> <p>1 that was instituted, if memory serves 2 correctly, in 2011.</p> <p>3 So as a corporate SOP, it 4 was something that was living within 5 Teva's system. It was not part of 6 Actavis's system in this specific form.</p> <p>7 Q. Right. And in this 8 paragraph, you don't say that you 9 reviewed any Actavis-specific quality 10 system SOPs prior to Actavis's 11 acquisition by Teva, correct?</p> <p>12 A. That is correct. The 13 serialization of SOPs, as they are, are 14 in a Teva format. But if I might just 15 refer to the list here, just to be 16 absolutely sure that in fact these all 17 have the CORP -- okay.</p> <p>18 I've seen the CORP 19 designation here for all of the Teva 20 SOPs. We have another SOP in here which 21 does not bear the CORP label to it.</p> <p>22 But -- and we also have 23 QAG-51 Actavis SOP on deviations of 24 nonconformance, which continues to be one</p>	<p style="text-align: right;">Page 80</p> <p>1 corporations.</p> <p>2 But deviations of 3 nonconformance, QAG-51, was one of 4 Actavis's SOPs that was continued to be 5 kept in its current form, and also 6 product complaints is another one, SOP 7 0197, which, again, does not have a Teva 8 corporate inventory -- SOP inventory 9 number to it.</p> <p>10 So I'll say that, what I'm 11 recalling from it, it may or may not be a 12 Teva inventory specifically.</p> <p>13 That could have been one 14 from an earlier -- an earlier company to 15 which that product complaint SOP 16 pertained.</p> <p>17 But again, deviations of 18 nonconformance was an Actavis SOP that 19 remains current within Teva's SOP 20 inventory system and denoted this way.</p> <p>21 So it's still a Teva SOP, as 22 much as Actavis is -- as we agreed it's 23 considered a Teva company. So it is 24 something which can be understood in that</p>
<p style="text-align: right;">Page 79</p> <p>1 which was utilized but does not appear to 2 have been updated into Teva's listing in 3 terms of formalization as a Teva SOP.</p> <p>4 There are some SOPs that 5 were carried forward at some of these 6 affiliate units here, and they are listed 7 here.</p> <p>8 Q. What are you referring to, 9 that you're looking at?</p> <p>10 A. I'm sorry.</p> <p>11 The -- I have a list of SOPs 12 that were comparing ones which -- 13 actually as informed by ones which John 14 Quick noted were examples of SOPs which 15 were relevant to governing quality 16 systems.</p> <p>17 I'm on Page 21 and 22 where 18 I've got a box that I've provided that 19 describes which SOP was operative for 20 which system.</p> <p>21 The CORP SOP designation 22 here would be one that was part of Teva's 23 main corporate level SOPs and extends 24 also to other Teva operating</p>	<p style="text-align: right;">Page 81</p> <p>1 sense.</p> <p>2 Q. Do you offer any analysis 3 anywhere in your report about which 4 Actavis quality policies were integrated 5 into Teva's policies upon acquisition?</p> <p>6 A. I don't have any specific 7 commentary with respect to that. Again, 8 there are -- this isn't meant to be a 9 complete list of all SOPs that Teva has.</p> <p>10 There are quite a number of 11 them. And some of the SOPs, clearly, 12 even as evidenced by this, were carried 13 over from the prior company and were 14 found to be suitable in the way that they 15 were composed.</p> <p>16 And Teva, for their reasons 17 that I don't know, elected to keep them 18 with the same serialization as they had 19 before.</p> <p>20 Q. You didn't do any analysis 21 as to which Actavis policies were 22 replaced by Teva policies upon Teva's 23 acquisition of Actavis, did you?</p> <p>24 A. I don't know that there were</p>

<p style="text-align: right;">Page 82</p> <p>1 policies, actually, that were different 2 with respect to Actavis and Teva. 3 The SOPs are things which 4 are reviewed periodically for their 5 accessibility, for operation, at that 6 particular site, because there are 7 site-specific SOPs for operations that 8 are unique to those sites. 9 So in terms of policy, one 10 can say that as soon as Actavis was 11 acquired by Teva, they came under the 12 control of the overall CORP-0001 13 corporate policy of Teva. 14 Q. So you're saying once 15 Actavis became part of Teva, the Teva 16 umbrella of CORP-designated SOPs, in your 17 view, was applied to the Actavis Malta 18 facility? 19 A. Correct. 20 Q. But other than the one 21 deviation Actavis policy you noted from 22 Paragraph 84 of your report, could you 23 tell us what, if any, Actavis policies 24 for quality continued to be in force upon</p>	<p style="text-align: right;">Page 84</p> <p>1 Q. Right. Other than a 2 specific Actavis policy that may be 3 mentioned in the body or your footnotes 4 of your report, you're not offering any 5 opinion on any Actavis policies up 6 through the point of acquisition by Teva? 7 A. I am not offering an opinion 8 there, no. 9 Q. Do you know if Actavis had a 10 policy on quality systems similar to 11 Teva's SOP CORP-0001 up to the point of 12 Actavis's acquisition by Teva? 13 A. I don't know what the 14 structure was that Actavis had in place. 15 Only knowledge of what these specific 16 SOPs are that were carried over, post 17 acquisition of Actavis. 18 Q. Other than the one Actavis 19 policy, you talked about earlier in 20 Paragraph 84 of your report, what other 21 Actavis policies were carried over and 22 remained in effect upon Actavis's 23 acquisition by Teva? 24 A. I have no direct</p>
<p style="text-align: right;">Page 83</p> <p>1 Teva's acquisition of Actavis? 2 A. Not down to that specific 3 level. 4 I only reviewed the SOPs 5 specifically for this comparison purpose, 6 again, against what John Quick had 7 detailed in his report. 8 And I did this for the 9 purpose of showing that John Quick made 10 it the point to say that these are the 11 types of SOPs that one should have in 12 place to govern these essential quality 13 system matters, that in fact there was 14 evidence that Teva companies had evidence 15 of these SOPs in place to govern these 16 quality system matters. 17 Q. And back to Paragraph 23, 18 where you reference Teva's SOP CORP-0001, 19 you didn't review any overarching Actavis 20 quality policies that were in effect up 21 to the point of Actavis' acquisition by 22 Teva, did you? 23 A. No, I made no such 24 comparison.</p>	<p style="text-align: right;">Page 85</p> <p>1 recollection of which ones were carried 2 over by Teva and deemed suitable enough 3 to continue with that kind of 4 documentation maintenance structure. 5 Q. And in fact, not only do you 6 not have any recollection, but you did 7 not undertake any analysis of which, if 8 any, Actavis policies carried over and 9 remained in effect upon acquisition by 10 Teva, right? 11 MR. HARKINS: Asked and 12 answered. 13 THE WITNESS: I did not 14 review every single Actavis SOP 15 that was in place that was carried 16 over by Teva. 17 But what I did speak to were 18 those specific SOPs that were 19 mentioned by John Quick as being 20 areas that companies should have 21 under control and governed by SOPs 22 as part of quality systems. 23 So I looked specifically at 24 only those SOPs.</p>

<p style="text-align: right;">Page 86</p> <p>1 BY MR. STANOCH:</p> <p>2 Q. How did you know that</p> <p>3 Actavis policy for handling of events and</p> <p>4 deviation investigations, as referenced</p> <p>5 in Paragraph 84 of your report, continued</p> <p>6 to remain in force and effect upon Teva's</p> <p>7 acquisition of Actavis?</p> <p>8 A. Well, one has to appreciate</p> <p>9 the fact that at the point in time that I</p> <p>10 asked what Teva's current SOPs were that</p> <p>11 governed these particular aspects here,</p> <p>12 in that the SOP is one that happens to</p> <p>13 have mentioned Actavis or possibly have</p> <p>14 some reference to Actavis there, in that</p> <p>15 Actavis as a company predated the</p> <p>16 acquisition by Teva, it is that SOP that</p> <p>17 was carried over as a procedure that was</p> <p>18 in place, established by Actavis in</p> <p>19 advance of Teva having acquired them.</p> <p>20 So at a time prior to Teva's</p> <p>21 acquisition, it's possible that that SOP</p> <p>22 could get looked at and a revision</p> <p>23 history could be drawn from the SOP, so</p> <p>24 you'd properly understand exactly when</p>	<p style="text-align: right;">Page 88</p> <p>1 deviations and nonconformance.</p> <p>2 Q. So the only policy that you</p> <p>3 received when you asked Teva for</p> <p>4 deviations and nonconformance which was</p> <p>5 the Actavis policy which you identify in</p> <p>6 Paragraph 84 of your report?</p> <p>7 A. I asked for what the current</p> <p>8 SOPs were for Teva, and this was supplied</p> <p>9 to me as a current SOP for Teva.</p> <p>10 Q. So it's your understanding</p> <p>11 that the legacy Actavis policy for</p> <p>12 deviations of nonconformance that you</p> <p>13 cite in Paragraph 84 of your report,</p> <p>14 applies to all Teva's facilities now?</p> <p>15 MR. HARKINS: Object to</p> <p>16 form.</p> <p>17 THE WITNESS: Well,</p> <p>18 certainly those that pertains to</p> <p>19 Actavis.</p> <p>20 I don't know to what extent</p> <p>21 the Actavis SOP is one that</p> <p>22 extends to other facilities. But</p> <p>23 this happens to be the way that</p> <p>24 Teva has chosen to serialize their</p>
<p style="text-align: right;">Page 87</p> <p>1 the SOP was implemented and how many</p> <p>2 different revisions it may have gone</p> <p>3 through before it exists in its current</p> <p>4 form.</p> <p>5 So there's a date certain</p> <p>6 that the SOP came into existence in that</p> <p>7 form, and maybe even superseded another</p> <p>8 SOP that wasn't named specifically called</p> <p>9 handling of events and deviations</p> <p>10 investigations. It may have been called</p> <p>11 something different at a point in time in</p> <p>12 the past by Actavis. But I'm not aware</p> <p>13 of what that SOP might have been or</p> <p>14 whether it's a predecessor.</p> <p>15 Q. I don't understand that,</p> <p>16 Mr. Anderson. I'd like you to explain a</p> <p>17 little more.</p> <p>18 Did you say that you asked</p> <p>19 for active policies and this is one that</p> <p>20 was provided?</p> <p>21 A. Correct.</p> <p>22 Q. You weren't given any policy</p> <p>23 that was a Teva CORP-designated policy?</p> <p>24 A. Not which pertained to</p>	<p style="text-align: right;">Page 89</p> <p>1 SOPs.</p> <p>2 And when I asked for what</p> <p>3 was the SOP that pertained to</p> <p>4 deviations of nonconformance, this</p> <p>5 was the SOP that was supplied to</p> <p>6 me.</p> <p>7 BY MR. STANOCH:</p> <p>8 Q. Is it your understanding</p> <p>9 that this SOP on deviations of</p> <p>10 nonconformance from Actavis would apply</p> <p>11 to Teva's Jerusalem facility that was</p> <p>12 making valsartan finished dose products?</p> <p>13 A. In that this was the SOP</p> <p>14 that was supplied to me, that is what I</p> <p>15 believe is the deviations of</p> <p>16 nonconformance SOP that is applied in</p> <p>17 Teva's company.</p> <p>18 Q. Right. So we're clear, the</p> <p>19 only policy that was given to you by Teva</p> <p>20 when you asked for a policy on deviations</p> <p>21 of nonconformance was the QAG-51B Actavis</p> <p>22 policy for handling deviations and</p> <p>23 investigations?</p> <p>24 MR. HARKINS: Object to</p>

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1 form. Vague.
2 THE WITNESS: To be clear,
3 this is not a policy. It is a
4 procedure.
5 SOP means standard operating
6 procedure. So I just want to be
7 very clear.
8 But I asked for standard
9 operating procedures, not
10 policies.
11 BY MR. STANOCH:
12 Q. Fair enough.
13 A. Policies are, again,
14 something that provide an environment
15 within which SOPs are generated. They
16 are not necessarily the SOP itself.
17 Q. So when you --
18 A. This is the SOP.
19 Q. So when you asked for the
20 standard operating procedure at Teva for
21 deviations of nonconformance, the only
22 operative policy they gave you was
23 QAG-51B Actavis SOP for handling
24 deviations investigations?

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1 MR. HARKINS: Object to
2 form. Vague. Asked and answered.
3 THE WITNESS: Correct.
4 BY MR. STANOCH:
5 Q. Are you aware of any Teva
6 SOP under the CORP designation or
7 otherwise, that would deal with handling
8 events and deviation investigations?
9 A. This is the only SOP that
10 was supplied to me from Teva when I asked
11 them for the Teva SOP that governed
12 deviations of nonconformance.
13 Q. So as far as you know, there
14 is no Teva-specific SOP for handling
15 deviation investigations and events other
16 than this policy from Actavis?
17 MR. HARKINS: Object to
18 form. Speculation.
19 You can answer if you know.
20 THE WITNESS: This is,
21 again, what is in Teva's inventory
22 here for governing deviations of
23 nonconformance. It happens to be
24 named QAG-51B. Its derivation

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1 happened to be from Actavis.
2 But to be clear, it's my
3 understanding that Actavis did not
4 just have one site that it owned
5 when it was a company. And when
6 Teva bought that site, or bought
7 that name, Actavis, bought that
8 company, it also bought the assets
9 that belonged to that and
10 facilities that belonged to that.
11 And this deviations of
12 nonconformance SOP applied to
13 Actavis companies.
14 So as it applied to Actavis
15 companies and the processes and
16 the products that were made by
17 Actavis which were now owned by
18 Teva, was clear that there was not
19 a name change that was applied to
20 the SOP and an incorporation of
21 any renaming of the SOP to fit the
22 CORP regimen of SOP inventory.
23 BY MR. STANOCH:
24 Q. Did you do anything to

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1 confirm that the Actavis SOP for handling
2 deviation investigations, QAG-51B,
3 applies to Teva facilities that were not
4 legacy Actavis facilities?
5 MR. HARKINS: Form. I'm
6 just going to instruct the witness
7 not to answer anything to the
8 extent it reflects conversations
9 with counsel.
10 You can answer.
11 THE WITNESS: Right. The --
12 when I made the request, I made
13 the request for the Teva SOP. And
14 Teva supplied this SOP to be
15 representative of the current SOP
16 for deviations of nonconformance.
17 If this in fact the current
18 Teva SOP, as was represented to me
19 as being the case, then I would
20 expect that this SOP applies also
21 to Teva's Jerusalem facilities,
22 although Teva was clearly in
23 possession of those facilities
24 under their name at a time prior

<p style="text-align: right;">Page 94</p> <p>1 to acquiring Actavis. 2 BY MR. STANOCH: 3 Q. And certainly, Actavis's SOP 4 for handling deviation investigations 5 would not have applied to any Teva 6 facility prior to Teva's acquisition of 7 Actavis, right? 8 A. That is correct. 9 Q. So you don't then cite any 10 SOP for deviation investigations at Teva 11 prior to Teva's acquisition of Actavis? 12 A. That's correct. 13 Q. Are you aware of any Teva 14 SOP for handling events and deviation 15 investigations that existed prior to 16 Teva's acquisition of Actavis? 17 A. I asked them for the current 18 SOP and they supplied the current SOP. 19 Q. Current as of when? 20 A. Current as of my request. I 21 guess that would have been either in 22 December of '21 or in January of '22. 23 Q. First, are you aware of any 24 Teva SOP for handling events and</p>	<p style="text-align: right;">Page 96</p> <p>1 in connection with the litigation. 2 It's all inappropriate. 3 He has indicated the 4 document he received, what he 5 relied on it for, and we're 6 getting way close to 7 attorney/client privilege here. 8 You can answer, if you can, 9 subject to the instruction not to 10 reflect any communicated with 11 counsel. 12 THE WITNESS: The purpose 13 for my asking for the SOPs 14 themselves was simply to provide 15 evidence of the fact that Teva had 16 necessarily, or has necessarily, 17 excuse me, SOPs in place that are 18 reflective of a quality system 19 that are governing these essential 20 points that John Quick had made in 21 his report. 22 So it was in direct 23 response, generally, to supporting 24 the fact that Teva has evidence of</p>
<p style="text-align: right;">Page 95</p> <p>1 deviation investigations that existed 2 prior to Teva's acquisition of Actavis? 3 MR. HARKINS: Object to 4 form. Asked and answered. 5 THE WITNESS: I have not 6 seen an SOP other than this one. 7 BY MR. STANOCH: 8 Q. And your requests, you said, 9 were for then-active Teva SOPs as of 10 December of 2021 or January of 2022; is 11 that right? 12 A. That is correct. 13 Q. You did not ask for copies 14 of Teva or Actavis SOPs that were in 15 effect during the relevant time frame at 16 issue in this litigation of 2012 to 2018? 17 MR. HARKINS: Object to 18 form. 19 Instruct the witness not to 20 answer to the extent that it 21 reflects communications with 22 counsel, the back-and-forth on 23 what he requested or was 24 represented to by counsel or Teva</p>	<p style="text-align: right;">Page 97</p> <p>1 the quality systems, as governed 2 by the SOP. 3 I did not intend to make any 4 kind of historic comparison of 5 what was available in times past, 6 because, again, my sole intention 7 was to show that, in fact, Teva is 8 a company that is governed by SOPs 9 that manage the quality system. 10 BY MR. STANOCH: 11 Q. Your understanding though, 12 is that the SOPs you cite in your report 13 are the current versions of those quality 14 SOPs, right? 15 A. Correct. 16 Q. You did not undertake to 17 analyze or review which, if any, of those 18 policies might have been in effect and in 19 what forms during the 2012 to 2018 time 20 period, correct? 21 A. The SOP that is in place 22 here for Actavis, and as I'm 23 understanding that when it pertained to 24 products that were manufactured by</p>

<p style="text-align: right;">Page 98</p> <p>1 Actavis, certainly this form of deviation 2 and nonconformance procedure applied 3 to -- applied to the Actavis facility, 4 which, again, was eventually acquired by 5 Teva. 6 So at the time that 7 valsartan drug products were being made 8 at the Arrow facility, which I understand 9 was at one time an Actavis facility, the 10 deviations of nonconformance that 11 pertained to that facility was in fact 12 this SOP, or a version of this SOP that 13 was current at that time. 14 Q. You did not cite or analyze, 15 though, any prior versions of the Actavis 16 QAG-51B SOP, other than the current 17 version, correct? 18 A. That is correct. 19 Q. And your answer a moment ago 20 focused on the QAG-51B Actavis policy. 21 It's correct, is it not, that you did not 22 undertake any analysis to determine 23 which, if any, of the Teva CORP policies 24 that you identify in your report might</p>	<p style="text-align: right;">Page 100</p> <p>1 effect when and in what forms during the 2 2012 to 2018 time period, did you? 3 MR. HARKINS: Object to 4 form. 5 The policies, he said, were 6 dated, and we're discussing these 7 without looking at them, including 8 the dates on which they would have 9 been effective. 10 But you can answer if you 11 recall. 12 MR. STANOCH: No need to 13 coach, Mr. Harkins. Please 14 refrain. 15 Objection to form only. 16 BY MR. STANOCH: 17 Q. Go ahead, Mr. Anderson. 18 A. We're capable of bringing up 19 each one of these individual SOPs with 20 their documentation that you should also 21 have in your possession. 22 And we can go through the 23 revision history to gain some 24 appreciation for when the SOPs themselves</p>
<p style="text-align: right;">Page 99</p> <p>1 have been in effect and in what forms 2 during the 2012 to 2018 time period, 3 correct? 4 A. I did not review that level 5 of detail as to when necessarily a 6 specific version of the corporate SOPs 7 came into existence. 8 What I do know is that the 9 CORP-0001 SOP, I did make a point to 10 seeing what was the overarching quality 11 philosophy that was going to be the 12 umbrella SOP, if you will, that was going 13 to be defining how quality systems were 14 structured. 15 And I do recall that that 16 SOP in its original form was initiated in 17 2011. 18 So it does, in fact, cover 19 the time during which valsartan products 20 were manufactured. 21 Q. Other than Teva standard 22 operating procedure CORP-0001, you did 23 not undertake any analysis to determine 24 which other Teva quality SOPs came into</p>	<p style="text-align: right;">Page 101</p> <p>1 were initiated. 2 Q. You yourself, sir, testified 3 that the SOPs in Paragraph 84 are the 4 current versions, as of a few months ago, 5 right? 6 A. Correct. 7 Q. And all I'm asking you, 8 because I don't see it anywhere in your 9 report -- and point to it if I'm wrong. 10 Nowhere in your report do 11 you opine as to which Teva quality CORP 12 SOPs came into effect when, and what they 13 say, do you? 14 A. I do not. But in that I 15 have referenced them here, and they are 16 in my footnotes, and named individually, 17 those documents can be pulled up if there 18 is a question that pertains to when, in 19 fact, they were initially employed. 20 Q. Sure. And if we pulled one 21 up and it said it came into effect 22 July 2019, right, that would mean that 23 you would not know anything as to what 24 that policy might have said prior to that</p>

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1 effective date, right?

2 MR. HARKINS: Form.

3 Speculation.

4 THE WITNESS: That is not

5 true. SOPs have a history, a

6 revision history, which is part of

7 the SOP, typically found at the

8 back of the SOP, which describes

9 what iterations of the SOP and

10 version of the SOP had existed in

11 the past, and often contain what

12 were the updates to that revision

13 that caused the issuance of a new

14 revision.

15 So you will get what the

16 date is, what the initial issuance

17 of what that SOP was, and when it

18 went into effect.

19 BY MR. STANOCH:

20 Q. But you don't opine anywhere

21 in your report, do you, as to what

22 revisions occurred, to what Teva policies

23 and when, correct?

24 A. I do not.

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1 Q. We'll get back to Teva

2 policies in a little bit.

3 Let's go to Paragraph 25 of

4 your report, sir. Tell me when you're

5 there.

6 A. I'm there. Yes. I'm there.

7 Q. Could you read this

8 paragraph for me?

9 A. Paragraph 25, "None of the

10 observations made during FDA's

11 inspections of Teva's or the relevant API

12 suppliers' facilities, nor Teva's own

13 observations made during audits of the

14 suppliers' facilities, prevented Teva

15 from identifying the NDMA or NDEA

16 impurities at issue in valsartan

17 medications, which were previously

18 unknown by both the industry and FDA

19 prior to Teva receiving notification of

20 the impurity from ZHP in June of 2018."

21 Q. Thank you.

22 And, you know, I want to

23 talk about some of the wording in this,

24 because there's a few clauses offset by

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1 commas in this paragraph, right?

2 A. There are.

3 Q. I think because -- if I read

4 it as, "None of the observations made

5 during the FDA's inspection of Teva's or

6 the relevant API suppliers' facilities

7 prevented Teva from identifying the NDMA

8 or NDEA impurities at issue in valsartan

9 medications"?

10 A. That is what I've written.

11 Q. Right. So you're saying

12 none of the observations prevented Teva

13 from identifying the NDMA or NDEA

14 impurities?

15 A. That's true.

16 Q. Right. So in other words,

17 the observations would have allowed Teva

18 to identify the NDMA or NDEA impurities

19 at issue?

20 MR. HARKINS: Object to

21 form. Misstates the testimony.

22 THE WITNESS: Again, as I'm

23 saying, these were previously

24 unknown by industry and FDA. And

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1 none of these audits or

2 inspections prevented Teva from

3 identifying NDMA or NDEA.

4 BY MR. STANOCH:

5 Q. Right. None of the

6 observations got in the way of Teva

7 identifying the NDMA or NDEA impurities

8 at issue, in valsartan, right?

9 MR. HARKINS: Object to

10 form. Misstates testimony.

11 THE WITNESS: As I'm stating

12 in my quotation here, none of the

13 observations prevented Teva from

14 identifying NDMA or NDEA.

15 BY MR. STANOCH:

16 Q. Okay. In Paragraph 27, you

17 start talking about Mr. Quick's report;

18 is that right?

19 MR. HARKINS: And, Dave,

20 we've been going over an hour. I

21 want to at least take a break at

22 some point shortly, check on our

23 tech issues and see if we have

24 anything better. So whenever you

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1 find it's time for a break.
2 MR. STANOCH: We were about
3 to flip the page.
4 BY MR. STANOCH:
5 Q. Mr. Anderson, would you like
6 to keep going for another 10 or 15 or
7 take a break? I'll let you decide.
8 A. I can take -- I can go on
9 for another ten minutes if you'd like.
10 But let us be sure to agree to have a
11 break in ten minutes.
12 Q. That's fine by me. So
13 Mr. Anderson, here you write,
14 "Mr. Quick's statement that FDA's
15 official position regarding cGMPs is that
16 if a company is not complying with cGMP
17 regulations, any drug it makes is
18 considered adulterated under the law, is
19 completely untrue and unsupported by the
20 materials relied upon by Mr. Quick."
21 Did I read that right?
22 A. You read that correctly.
23 Q. And I should have clarified
24 this earlier, but as you used it in your

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1 report, cGMP stands for current good
2 manufacturing practices, right?
3 A. Correct.
4 Q. So it's your view then that
5 a company not complying with cGMP does
6 not render the company's drugs
7 adulterated?
8 A. The statement that Mr. Quick
9 has drawn -- made this conclusion from,
10 is what I'll consider a cherry-picked
11 statement. It is a very general
12 statement that is made, not in a policy
13 document by FDA. It is something that
14 exists in an information web page as it
15 pertains to this.
16 But the context in which
17 this statement appears does not appear in
18 Mr. Quick's citation of this portion
19 here.
20 So it's -- it is an
21 incomplete rendering. And it is not a
22 statement of FDA quote-unquote official
23 policy.
24 Q. You know, with all due

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1 respect, Mr. Anderson, you don't really
2 say any of that in your report. You say
3 that Mr. Quick's statement is completely
4 untrue and unsupported, don't you?
5 A. I do.
6 MR. STANOCH: Stand by.
7 Please pull up Exhibit 3. Let me
8 know when you're there.
9 (Document marked for
10 identification as Exhibit
11 Anderson-3.)
12 MR. HARKINS: It will be in
13 the DropBox. So go here and hit
14 X. Now refresh the page. Great.
15 Yeah, when you exit out, make sure
16 not to exit out of the whole
17 thing. Just exit out of the inner
18 window.
19 THE WITNESS: I hit the
20 three document, but --
21 MR. HARKINS: It's loading.
22 MR. STANOCH: I can try to
23 move this along while it's
24 loading, sir. Hopefully the

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1 document will load. I can try to
2 share my screen just to move this
3 along.
4 BY MR. STANOCH:
5 Q. Can you see my screen, sir?
6 A. Yes. It says David Stanoch
7 has started screen sharing. I cannot see
8 a document yet.
9 Q. You don't see a document?
10 A. I don't see a document. No.
11 MR. HARKINS: Let me make
12 sure that he's not pinned to a
13 different screen.
14 THE WITNESS: Ah, here we
15 go.
16 MR. HARKINS: Here we go.
17 BY MR. STANOCH:
18 Q. And again, you can access
19 the full document once it's available on
20 the folder.
21 But for now, on my screen,
22 you can see the document entitled "Facts
23 About the Current Good Manufacturing
24 Practices," cGMPs?

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1 A. I see that, yes.
2 Q. Have you seen this document
3 before, sir?
4 A. I have seen this document.
5 Q. All right. And it's from
6 the FDA, correct?
7 A. It is -- it appears to be
8 the rendering that was from an online
9 source supplied by FDA.
10 Q. Right.
11 A. I don't see FDA's name, for
12 instance, in the link that you have above
13 there.
14 Q. Well, the link is obviously.
15 Right, the -- I'm sorry. Go ahead. I'm
16 sorry. I apologize. Where were you
17 looking?
18 A. I'm looking at the very
19 first line where it says, "Pharmaceutical
20 quality/drug development approval
21 process." It doesn't say FDA in that.
22 This looks familiar to me
23 from something that I have seen supplied
24 on the FDA website. But it's not obvious

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1 that it's necessarily from FDA in the
2 form that you have it here.
3 For instance, you have not
4 brought me to the website, the FDA's
5 formal website. This is a reproduction
6 of something that appears that was on the
7 website.
8 Q. Right.
9 A. I can't -- it's not an FDA
10 document. Okay. I'm just making that
11 clear.
12 Q. All right. That's fair.
13 You understand that we're not in a
14 dynamic situation where I'm pulling up
15 live websites as we go, right? You
16 understand that?
17 A. I understand only what you
18 told me here. I didn't know that that
19 was not a possibility that you had.
20 Q. Right. And, you know, if we
21 need to do that, we'll start doing that.
22 But for now, this is something that we
23 did pull from the FDA website. And I'll
24 represent that to you.

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1 And you're familiar --
2 regardless, you're familiar with this
3 being something from the FDA website,
4 right?
5 A. This appears to be from the
6 FDA website.
7 Q. And you see this section
8 here, it says, "If a manufacturer is not
9 following cGMPs, are drugs safe for use?"
10 Do you see that?
11 A. Yes.
12 Q. And read that first sentence
13 for me.
14 A. At the bottom of this page
15 here? Or do you have -- there we go. We
16 have more of the document. Let's move
17 the document up here.
18 So, "If a manufacturer is
19 not following cGMPs, are drug products
20 safe for use?"
21 Could you move that to the
22 top of your page so we include the entire
23 narrative?
24 Q. How's that?

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1 A. Keep going. The narrative
2 continues below the page, and I don't see
3 that. Is there a way to move that up?
4 There we go. Okay. Here we
5 go.
6 Q. Again, the question is,
7 could you read that first sentence?
8 A. Yeah. Happily.
9 The first sentence as it
10 reads is: "If a company is not complying
11 with cGMP regulations, any drug it makes
12 is considered 'adulterated' under the
13 law."
14 Q. Right. And as your
15 Paragraph 27 notes, Mr. Quick is quoting,
16 "If a company is not complying with cGMP
17 regulations, any drug it makes is
18 considered 'adulterated' under the law."
19 Correct?
20 A. That is a statement that is
21 made here and that Mr. Quick is relying
22 upon.
23 Q. Right. So it's not then
24 that his statement was completely untrue

<p style="text-align: right;">Page 114</p> <p>1 and unsupported, right? Because we're 2 looking at something that he took it 3 verbatim from, from the FDA website, 4 correct? 5 A. He took this statement from 6 the FDA website, but it is not taken in 7 the full context in which it exists. 8 And that is the reason, 9 because it doesn't take in account the 10 full context, it is unsupported. 11 Q. Well, you don't say that in 12 Paragraph 27, do you? 13 A. Well, standing on its own, 14 it is not the complete context within 15 which this statement resides. And if 16 you're only telling half the story, and 17 not the whole story, that's half the 18 truth and not the full truth. 19 So in that sense, it is not 20 a truthful statement. It merely just 21 cherry-picks and cuts that statement out 22 of there, as though that is the only 23 representation of what FDA's official 24 position is.</p>	<p style="text-align: right;">Page 116</p> <p>1 completely untrue and unsupported, right? 2 MR. HARKINS: Object to 3 form. Asked and answered. 4 THE WITNESS: The statement 5 characterized as FDA's official 6 policy is untrue. Completely. 7 BY MR. STANOCH: 8 Q. You're agreeing though that 9 he's accurately quoting this sentence in 10 his report, right? 11 A. I'm not challenging that he 12 hasn't accurately quoted the sentence. 13 My challenge is it's 14 completely untrue to say that that is the 15 sole statement of what forms FDA's 16 official policy. That is untrue. And it 17 is unsupported, particularly in the fact 18 that there is context which surrounds the 19 way that sentence should be appreciated. 20 Q. And nothing in your 21 Paragraph 27 says anything about context, 22 right? 23 Do you see any mention of 24 context in your Paragraph 27?</p>
<p style="text-align: right;">Page 115</p> <p>1 Q. So you're disagreeing that 2 Mr. Quick quoted this sentence 3 accurately? 4 A. He quoted the sentence 5 alone. He did not quote it in context; 6 hence, it is unsupported. 7 And because it is not quoted 8 in context, it is not entirely true as a 9 standalone statement. 10 Q. Right. Well, not entirely 11 true is not the same as completely untrue 12 and unsupported, is it, sir? 13 A. It is certainly unsupported 14 because it is out of context and it is 15 untrue if just held -- and held this 16 sentence alone, as he chose to quote it, 17 and to then characterize that as FDA's 18 official position. 19 Q. Mm-hmm. And you take 20 Mr. Quick to task for exaggerations. But 21 then it sounds like, Mr. Anderson, you're 22 exaggerating in Paragraph 27 when you say 23 this accurate verbatim quotation of a 24 sentence from the FDA web website is</p>	<p style="text-align: right;">Page 117</p> <p>1 A. I have not used that word. 2 Q. Right. And do you reference 3 any of that so-called context in 4 Paragraph 27 that you now say is missing? 5 A. I speak to it later in the 6 report, where I take this whole matter 7 apart, and I do furnish what the context 8 is within which this opening statement 9 appears. 10 Q. We'll get to that part. 11 And if you look at Paragraph 12 28, in part you note the FDA's guidance 13 with respect to the presence of NDMA and 14 NDEA. 15 Do you see that? 16 A. I see that. If you'd like 17 to read it. 18 Q. You can read it to yourself. 19 My question about that 20 guidance is, that's the guidance issued 21 when? 22 A. Well, Paragraph 28 opens 23 with Mr. Quick's statement that valsartan 24 products containing NDMA and impurities</p>

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1 were misbranded is similarly incorrect
2 and unsupported.
3 May I continue?
4 Q. I'm not asking you to read,
5 Mr. Anderson. I'm focused on your
6 reference to FDA's guidance in the last
7 sentence of that paragraph.
8 Do you see that?
9 A. Very good. Starting at,
10 "Moreover." Is that correct?
11 Q. That's where I am, sir,
12 absolutely. And I'm asking, which
13 guidance is that, sir?
14 A. Okay. FDA's guidance with
15 respect to NDMA and NDEA is the current
16 guidance that was published in its latest
17 form in February 2021.
18 Q. And when was that guidance
19 first published?
20 A. Guidance was first published
21 back in, I believe it was December of
22 2018, when interim impurities --
23 acceptable impurity levels for these NDMA
24 and NDEA were communicated.

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1 Q. And prior to December of
2 2018, were there any guidance from the
3 FDA allowing any amount of nitrosamines
4 in valsartan or any other drug products?
5 A. FDA specifically had not
6 communicated a guidance having the
7 name -- having to do with nitrosamine
8 content in drug products.
9 Q. Absent an interim limit for
10 nitrosamines prior to December 2018, then
11 the allowable limit was zero, correct?
12 A. That's not correct as you've
13 stated it. It simply meant there was no
14 limit specified, not that the allowable
15 limit was zero.
16 Q. Mm-hmm. So the FDA never
17 set any allowable limit prior to December
18 of 2018 for nitrosamines, right?
19 A. Not formally, no.
20 Q. Informally?
21 A. Not even informally. There
22 was what was the governing standard by
23 which applications that Teva had for
24 valsartan at that time governed the

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1 presence of impurities as they might be
2 evaluated against standards that were
3 communicated in ICH -- that's
4 International Conference of
5 Harmonization, ICH, Value Q3A.
6 Q. There was never an allowable
7 limit for nitrosamines in drug products
8 per the FDA until December of 2018,
9 right?
10 A. Not one specified, no.
11 Q. Rather than getting into the
12 ICH, let's take that break Mr. Anderson.
13 A. Very good. Thank you.
14 THE VIDEOGRAPHER: The time
15 right now is 11:17 a.m. We are
16 off the record.
17 (Short break.)
18 THE VIDEOGRAPHER: The time
19 right now is 11:33 a.m. We're
20 back on the record.
21 BY MR. STANOCH:
22 Q. Welcome back, Mr. Anderson.
23 Just yes or no, did you talk to your
24 counsel during the break?

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1 A. Yes.
2 Q. Did you review any
3 documents?
4 A. None.
5 Q. Did you talk or communicate
6 in any way, text, e-mail, phone,
7 otherwise, with anyone besides
8 Mr. Harkins at the break?
9 A. No.
10 Q. Great.
11 You're familiar with the
12 term "adulteration," right?
13 A. I am.
14 Q. Right. And what's your
15 understanding of an adulteration of a
16 drug?
17 A. Adulteration is defined in
18 law in the FD&C Act. It is also found in
19 regulations, specifically at 21 C.F.R.
20 210 that defines adulteration as any --
21 excuse me.
22 May I actually bring up the
23 specific quotation from 210 and read it
24 so that I do this accurately?

<p style="text-align: right;">Page 122</p> <p>1 Q. I don't need you to read 2 from memory, sir. We can say, fair 3 enough that you agree with the term 4 "adulteration" as it's defined in statute 5 and regulations? 6 A. Yes. 7 Q. And can a drug be 8 adulterated even if it was AB-rated? 9 A. Yes. 10 Q. Do you agree that drugs 11 could be adulterated even if they do not 12 contain any contaminants or impurities? 13 A. Yes. 14 Q. For instance, a drug could 15 be found to be adulterated if it was 16 manufactured in a way that was not in 17 conformance with current good 18 manufacturing practices, right? 19 A. I agree with that. 20 Q. And do you agree that 21 adulteration can occur absent official 22 action indicated by the FDA? 23 A. Adulteration is a 24 determination that FDA themselves make.</p>	<p style="text-align: right;">Page 124</p> <p>1 A. That's not what I said. I 2 said there is a point in time at which 3 FDA determines that a drug product or 4 substance is in their -- and then 5 declared to be adulterated. 6 Q. Right. And the fact of 7 adulteration can be existent prior to the 8 FDA determination, correct? 9 A. Adulteration is an 10 interpretation that is made by FDA with 11 respect to the drug product or drug 12 substance. And it is pertinent to the 13 point in time at which FDA thinks that is 14 the case. 15 Q. When the FDA makes the 16 determination that a drug is adulterated, 17 is that a prospective only determination? 18 A. That would be from a 19 specific point in time and going forward 20 thereafter. 21 Q. And the FDA can choose a 22 point in time for adulteration that 23 predates the date of the FDA's opinion, 24 correct?</p>
<p style="text-align: right;">Page 123</p> <p>1 THE COURT REPORTER: I think 2 we lost defense counsel. 3 MR. STANOCH: Stand by. 4 (Whereupon a discussion was 5 held off the record.) 6 BY MR. STANOCH: 7 Q. Mr. Anderson, you agree that 8 the FDCA and C.F.R. regulations 9 concerning adulteration make no mention 10 of official action indicated prior to the 11 existence of adulteration, yes? 12 A. FDA determines adulteration 13 at a specific point in time. The law, as 14 you've quoted it there, does not speak to 15 a specific point in time, merely the fact 16 that adulteration can exist given certain 17 conditions, and FDA will make that 18 determination at that time whether 19 adulteration is -- rises to -- that 20 adulteration -- it rises to the level of 21 adulteration. 22 Q. A drug product can be 23 adulterated then prior to the FDA's 24 saying so, correct?</p>	<p style="text-align: right;">Page 125</p> <p>1 A. FDA determines from a 2 specific date, and they communicate what 3 that specific date is that they made that 4 determination. 5 Q. I'm sorry. Are you talking 6 about a specific date of the FDA's 7 determination? Or are you saying a 8 specific date that the FDA believes from 9 which adulteration existed? 10 A. The specific date that FDA 11 communicates that a product or an API is 12 adulterated. 13 Q. So if the FDA issues a 14 statement today, March 9, 2022, that a 15 drug product has been adulterated, you 16 can certainly say that it's been 17 adulterated for some period of time up to 18 today, correct? 19 A. FDA does not say that in the 20 context of valsartan. 21 Q. Well, I'm not talking about 22 that context specifically, sir. All 23 right. 24 In my hypothetical, today,</p>

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1 March 9, 2022, FDA issues a statement
2 that a drug product has been adulterated.
3 It can certainly say that it's been
4 adulterated for some period of time up to
5 today, correct?
6 MR. HARKINS: Form.
7 Hypothetical.
8 You can answer.
9 THE WITNESS: It is
10 hypothetical. In my experience
11 I've not read FDA makes a
12 declaration of that type that I
13 have read.
14 BY MR. STANOCH:
15 Q. So you're saying that a drug
16 that might have been contaminated and
17 adulterated because of that, is not
18 adulterated up until the time that the
19 FDA says adulteration, and all the sales
20 prior to that date were not adulterated?
21 A. You have to be careful with
22 your use of terms here. You have said
23 the word contaminant.
24 I believe we are not talking

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1 about a contaminant here.
2 We're talking about a
3 process impurity. There is a difference.
4 Q. Again, you're saying that a
5 drug that has been contaminated for years
6 up until March 9, 2022, until the FDA
7 issues a letter saying adulteration,
8 you're saying all the drug products sold
9 prior to that letter of today was not
10 adulterated?
11 A. You'll need to quote a
12 statement from FDA specifically saying
13 that a product is as you have described
14 it and what the context of that is.
15 Q. So you can't tell me sitting
16 here today, whether -- when the FDA says
17 a product is adulterated, you're saying
18 that it cannot, it does not say that's a
19 retrospective determination?
20 MR. HARKINS: Object to
21 form. Misstates the testimony.
22 THE WITNESS: Respectfully,
23 Mr. Stanoch, you used the term
24 "has been," and as a -- what is

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1 that -- past-perfect use of that.
2 It is not the present tense.
3 And the FDA is speaking of
4 valsartan in the present tense as
5 they describe in their warning
6 letters that were issued, the
7 first one being issued with
8 respect to ZHP mentioning that
9 valsartan API is or are --
10 products are adulterated.
11 So as of that point in time,
12 November 29th, I believe it was,
13 2018, when that warning letter was
14 issued, as of that point in time,
15 from that point forward,
16 adulteration is the
17 characterization of the APIs made
18 by ZHP.
19 BY MR. STANOCH:
20 Q. Part of that issue with ZHP
21 was nonconformance with cGMP, correct?
22 A. There were cGMP observations
23 that FDA made.
24 Q. About ZHP's processing of

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1 valsartan API, right?
2 A. There were 483s that were
3 initially issued. But the warning letter
4 that was the outcome of FDA's
5 investigation after having received ZHP's
6 response and having performed assays on
7 drug substances that they collected from
8 ZHP, FDA determined that as of
9 November 29, 2018, ZHP's products are
10 adulterated, valsartan products are
11 adulterated.
12 Q. So all -- I apologize.
13 So all the valsartan API
14 product that was being manufactured under
15 the same deviations from the cGMP, none
16 of that was adulterated until
17 November 29, 2018, that's your
18 testimony?
19 A. Correct.
20 Q. And the exact same facts
21 that the FDA would cite in the
22 November 29th, 2018 letter could have
23 existed -- in fact, did exist prior to
24 that date, as to valsartan API, right?

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1 MR. HARKINS: Form. Facts
2 not in evidence.
3 THE WITNESS: As we've said,
4 there is a date upon which FDA
5 declares that drug substance or
6 product is adulterated. They did
7 so on November 29th, 2018, and not
8 at a time before that.
9 BY MR. STANOCH:
10 Q. Right. You agree, though,
11 that the facts that led the FDA to issue
12 its declaration on November 29, 2018,
13 existed prior to that date, correct?
14 MR. HARKINS: Object to
15 form.
16 THE WITNESS: There was a
17 fact-finding exercise that FDA
18 underwent in order to make that
19 final declaration on November 29,
20 2018, to say that ZHP's products
21 are adulterated.
22 BY MR. STANOCH:
23 Q. And that fact finding
24 occurred prior to November 29, 2018,

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1 correct?
2 A. Correct.
3 Q. And the facts that were
4 found occurred prior to November 29,
5 2018, correct?
6 A. Correct.
7 But the point is, the
8 product was not declared adulterated
9 until November 29, 2018, which is the
10 important point.
11 Q. Well, every fact underlying
12 the FDA's decision on November 29, 2018,
13 existed prior to that date, correct?
14 MR. HARKINS: Object to
15 form. Vague.
16 THE WITNESS: The body of
17 data and observations that they
18 had to inform what their final
19 determination and declaration with
20 respect to adulteration of, were
21 events which occurred in advance
22 of declaring that adulteration on
23 11/29/2018.
24 At no point -- at no time

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1 prior to that did FDA declare
2 valsartan API products made by ZHP
3 or by Teva, for that matter, as
4 adulterated.
5 BY MR. STANOCH:
6 Q. There was no question
7 pending there. So I appreciate you to
8 confine your answers that way and not
9 spontaneously speak, Mr. Anderson. But
10 that's neither here nor there.
11 When did the FDA learn of
12 the events which led to its declaration
13 on November 29, 2018, as to ZHP's
14 valsartan API?
15 A. According to the information
16 request that was satisfied by ZHP in
17 2018, which was made by the FDA, I recall
18 reading in that information request that
19 ZHP became aware of NDMA on or about
20 June 6, 2018.
21 Q. You talk about this a little
22 in your report in the context, I think,
23 of referencing -- was it Mr. Tony
24 Binsol's testimony?

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1 Do you recall that?
2 A. If you could point me to the
3 paragraph that you're referring to, I'll
4 be happy to speak to it.
5 Q. Sure.
6 MR. STANOCH: Stand by.
7 BY MR. STANOCH:
8 Q. Look, starting around
9 Paragraph 95 and 96. Tell me when you're
10 there.
11 A. I'm at Paragraph 95 and 96.
12 Q. And here you're talking
13 about bullets in Mr. Quick's report; is
14 that right?
15 A. Paragraph 95 begins with
16 statements which were attributable to
17 Mr. Binsol, and the reason that I
18 reviewed those statements were because
19 Mr. Quick refers to this testimony.
20 Q. Right. And you agree in
21 Paragraph 95 that Mr. Quick's bullets,
22 which rely on Mr. Binsol's testimony are,
23 in your words, "The common and current
24 understanding in the pharmaceutical

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1 industry for what constitute the general
2 expectations made of API suppliers, and
3 in this specific case of Teva's suppliers
4 of valsartan API."
5 Right?
6 A. Correct.
7 Q. Okay. And you agree with
8 Mr. Binsol's setting forth of the general
9 expectations, right?
10 A. Could you be more specific,
11 please?
12 Q. Well, Mr. Quick had, you
13 know, one through eight in his paragraph
14 about common and current understanding
15 for the general expectation made of API
16 suppliers. And he cited to Mr. Binsol,
17 right?
18 A. He did.
19 Q. And then in Paragraph 96,
20 you talk a little bit more about those
21 same statements, right?
22 A. I do.
23 Q. Right. And you agree with
24 Mr. Binsol's testimony about the general

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1 expectations of API suppliers,
2 specifically Teva's suppliers of
3 valsartan API, right?
4 A. Correct.
5 Q. And in Paragraph 96, you go
6 on to say that -- you identify that some
7 of the statements attributable to
8 Mr. Binsol were about the obligations of
9 an API manufacturer to internally control
10 and document their processes.
11 A. That is an expectation.
12 Q. And you agree with that
13 expectation, right?
14 A. I do.
15 Q. And then you also speak
16 about some of the statements attributed
17 to Mr. Binsol about an API supplier's
18 obligation to promptly inform API
19 customers of the potential or suspected
20 presence of genotoxic impurities which
21 the API supplier identifies in the API,
22 right?
23 A. Correct.
24 Q. And you agree with those

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1 obligations as well, correct?
2 A. I'm sorry. I didn't hear.
3 What kind of obligations?
4 Q. The supplier's -- API
5 supplier's obligations, as you refer to
6 them in your Paragraph 96.
7 A. Exactly true. Yes.
8 Q. And the only -- you say the
9 only thing that you would add to the
10 expectations of an API supplier, to those
11 that Mr. Binsol identified was that, "An
12 API customer of any potential or
13 suspected not previously known or
14 characterized impurity by the
15 manufacturer, however determined, whether
16 arising from a customer complaint or a
17 health authority notification or solely
18 by an investigation accomplished at the
19 API manufacturer as described, and not
20 just of genotoxic impurities which it
21 detected, should constitute a reason for
22 notifying the API manufacturer's relevant
23 customer base."
24 Did I read that correctly?

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1 A. You did read that correctly.
2 Q. And the gist of this is that
3 the only thing that you would add to the
4 eight points above that were attributable
5 to Teva's Mr. Binsol, was about this one
6 about an API customer's obligation to
7 notify its customers of any potential or
8 suspected impurities, genotoxic or not?
9 A. That is what Paragraph 97 is
10 intending to convey, correct.
11 Q. Then you go on to discuss,
12 as you understand it, when ZHP first
13 informed Teva about the NDMA issues in
14 valsartan API, right?
15 A. Could you rephrase that
16 question for me, please?
17 Q. Sure. And then starting on
18 Paragraph 98 of your report, you start to
19 discuss when Teva first learned from ZHP
20 of the NDMA issue with valsartan API?
21 A. That is correct.
22 Q. And I think you say here
23 that ZHP first learned of the presence of
24 NDMA in ZHP's API, from ZHP, on June 20,

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1 2018?

2 A. Correct. That is my

3 understanding.

4 Q. And I think you said earlier

5 today, and you can correct me if I'm

6 wrong, that ZHP was made aware of the

7 potential for NDMA by another customer in

8 June 6th of 2018?

9 A. June 6, 2018, is the date,

10 as I recall it, from the response to the

11 information request made to FDA in August

12 of 2018.

13 Q. And who is the customer then

14 that raised the NDMA issue with ZHP in

15 early June of 2018?

16 A. That was never made known to

17 me at the time that I prepared this

18 report.

19 Subsequent to that, as I

20 have been reading Mr. Quick's report, he

21 has said that it is Novartis that was the

22 one who determined by way of ZHP that

23 NDMA existed.

24 Q. And you were not aware of

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1 that fact until after you had issued your

2 report?

3 A. That's correct.

4 Q. And have you since

5 investigated for yourself whether it was

6 in fact Novartis who informed ZHP about

7 the NDMA issue in ZHP's valsartan API?

8 A. I have not pursued that, no.

9 Q. Do you know how Novartis was

10 able to detect NDMA in ZHP's Valsartan's

11 API?

12 A. I do not know what method

13 they employed to make that determination.

14 Q. Do you know how Novartis was

15 able to detect NDMA in ZHP's valsartan

16 API while other ZHP customers, such as

17 Teva, had not done so to that point?

18 A. I do not know how it was

19 that Novartis became aware of NDMA or

20 what the method was that they used

21 specifically that was different than ones

22 which were methods for qualifying API for

23 impurities, according to the way that the

24 applications themselves were approved by

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1 FDA.

2 Q. Because you have not

3 undertaken to analyze how Novartis was

4 able to detect NDMA in the valsartan API,

5 you're not offering any opinion, one way

6 or the other, on whether Teva should have

7 detected it as well, are you?

8 MR. HARKINS: Object to

9 form.

10 THE WITNESS: Again, I don't

11 know exactly which method Novartis

12 used to detect NDMA in valsartan

13 that was obtained from ZHP.

14 BY MR. STANOCH:

15 Q. And so you don't know if

16 Teva was employing the same testing

17 methods as Novartis at the time on

18 June 2018 for valsartan API, do you?

19 A. I don't know what the method

20 was that Novartis was using.

21 There was an approved method

22 that was validated that Teva was

23 employing to assess the purity of drug

24 substance received from -- received from

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1 ZHP and also, for that matter, from

2 Mylan.

3 But I do not know in what

4 specific ways Teva's methods differed

5 from the one that Novartis employed to

6 evaluate the product that they examined.

7 I have no idea which method they used.

8 Q. Do you agree that a drug

9 finished dose -- strike that.

10 Do you agree that a finished

11 dose drug manufacturer is responsible for

12 the APIs used in their finished dose

13 product?

14 A. They are responsible for the

15 API used in their drug product and it

16 must conform to specifications that have

17 been approved in their application.

18 Q. So, Teva, from a quality

19 perspective, as a finished dose

20 manufacturer, was ultimately responsible

21 for the valsartan API that it used from

22 ZHP or Mylan, correct?

23 A. It has to utilize API that

24 conforms with specifications that were

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1 agreed to with FDA at the time of the
2 approval of the drug product or at a
3 subsequent time when supplemental
4 applications may have been filed to
5 update that ANDA.
6 Q. Do you disagree then that
7 Teva was ultimately responsible for any
8 quality issues for the valsartan API it
9 was incorporating into its own finished
10 dose valsartan product?
11 MR. HARKINS: Objection.
12 Asked and answered.
13 THE WITNESS: It was
14 required to verify that the API
15 that they were using was of the
16 quality that was expected and
17 satisfied conformance to the
18 specifications that they had,
19 which were purchasing
20 specifications, which also
21 mirrored those which were the
22 approved specifications that FDA
23 reviewed and granted approval for
24 their application based on.

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1 BY MR. STANOCH:
2 Q. Did Teva -- strike that.
3 Did ZHP first learn about
4 the potential for nitrosamines in
5 valsartan API from Novartis on June 6,
6 2018?
7 A. That is the document to
8 which I referenced, and I believe that
9 ZHP has an obligation to make statements
10 to FDA which are truthful, and they
11 attest to that fact. So on that basis,
12 I'm accepting of that date that they
13 communicated.
14 Q. If ZHP knew about for --
15 strike that.
16 So if ZHP knew of a
17 potential or suspected nitrosamine
18 impurity in valsartan API at an earlier
19 date, it would be your expectation that
20 ZHP would inform its customers such as
21 Teva, correct?
22 MR. HARKINS: Object to
23 form. Speculation.
24 THE WITNESS: The approved

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1 specifications for valsartan API
2 are ones which were in force for
3 Teva as a product manufacturer.
4 And if there were impurities
5 which rose above which were those
6 that were required -- those that
7 were appearing at levels above
8 those that were required by ICH
9 Q3A, it would be incumbent upon
10 the API supplier to communicate
11 that to the customer, in this
12 case, ZHP communicating such a
13 thing to Teva.
14 That was not the case here.
15 BY MR. STANOCH:
16 Q. Let's be more pointed,
17 Mr. Anderson.
18 If ZHP knew about the
19 potential for nitrosamines in valsartan
20 APIs prior to June of 2018, would it have
21 been incumbent upon them to notify Teva,
22 its customer?
23 A. Not necessarily.
24 Q. So ZHP, if it, in your

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1 words, knew of a potential or suspected
2 not previously known impurity, it did not
3 have to notify Teva?
4 A. Not necessarily.
5 Q. Even if that's a
6 nitrosamine?
7 A. Not necessarily.
8 Q. So what circumstances to you
9 then would ZHP have to inform Teva of a
10 potential or suspected nitrosamine
11 impurity in valsartan API it was selling
12 to Teva?
13 A. FDA approved the
14 application, the valsartan application
15 for Teva based on the specifications for
16 the API such as they were supplied by ZHP
17 and Mylan to Teva for utilization in
18 valsartan products.
19 The impurity profile that
20 was operative at that time was based on,
21 as many API manufacturers who were
22 expected to conform to and currently are,
23 is ICH Q3, where the reporting threshold
24 of impurities in API is set at a place

<p>Page 146</p> <p>1 where 0.05 percent is the threshold. 2 Below that threshold, that 3 was not a requirement for ICH Q3A. The 4 conformance of ICH Q3A was the 5 requirement for the approval of the 6 valsartan application. 7 That's not to say that ZHP 8 could not have undertaken their own 9 research and development to study their 10 valsartan processes even more thoroughly 11 than what was required for approval and 12 for meeting purchasing specs for Teva. 13 So again, nothing prevented 14 them from doing research and development. 15 And it may be that there were, depending 16 on studies that were done and whatever 17 the conditions of those studies as they 18 were performed, there may have been side 19 reactions that were identified that gave 20 rise to impurities at a level which fell 21 below that required reporting level, and 22 then one would be doing more R&D for 23 further characterizing as to what the 24 nature of those impurities were and how</p> <p>Page 147</p> <p>1 consistent it was an impurity to have 2 formed. 3 There are a lot of things 4 that go into an investigation of this 5 type. But these are things which happen 6 inside of ZHP. It is not the instant -- 7 it's not instantly necessary for the 8 manufacturer of API to inform a customer 9 of impurities which fall below what are 10 ICH qualifiable and quantifiable and 11 reportable impurities, which was the 12 regulatory metric that FDA employed to 13 approve and allow the marketing of 14 valsartan products. 15 Q. You agreed this morning that 16 nitrosamines fall in the cohort of 17 concern, didn't you? 18 A. I did. 19 Q. Right. And under the ICH 20 guidelines that you're referencing, a 21 cohort of concern should have materials 22 assessed because they might test at lower 23 thresholds than normal thresholds, 24 correct?</p>	<p>Page 148</p> <p>1 A. But I'll also be clear on 2 that, that ICH Q3A where you're quoting 3 that stipulation from does not specify 4 levels at which potentially high potency 5 or other toxic substances would be 6 limited. They do not specify any limits 7 for them. 8 Q. That's right. They put the 9 obligation on the manufacturer, and in 10 this case, the API manufacturer, to 11 properly characterize and assess an 12 impurity that falls within the cohort of 13 concern, don't they? 14 A. That would be the obligation 15 of the API manufacturer. 16 Q. Do you think Teva would have 17 wanted to know about the nitrosamine 18 impurities sooner, if ZHP knew about them 19 sooner than June 6, 2018? 20 MR. HARKINS: Objection to 21 form. Vague. 22 THE WITNESS: What I'm 23 hearing, and the way that I'm 24 interpreting, was the information</p> <p>Page 149</p> <p>1 request response that ZHP made 2 to -- made to FDA, is as of that 3 date, June 6, 2018, that ZHP was, 4 at that time, at that point in 5 time then thoroughly convinced 6 that what they were seeing in 7 their valsartan API was identified 8 accurately and at levels that they 9 had confirmed. 10 It was likely within a range 11 of values that they had selected 12 from an assortment of APIs that 13 were under examination. 14 And at that one point in 15 time finally at which they were 16 convinced, they then, as I 17 understand it, or as I recall it, 18 is when they informed -- began to 19 initiate informing the API 20 customers of theirs, and upon 21 which then roughly two and a half 22 weeks later, Teva was notified 23 formally by ZHP who said that they 24 were working with FDA on this</p>
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1 issue, that the presence of NDMA
2 had been identified in their
3 valsartan drug substances.
4 BY MR. STANOCH:
5 Q. Had you seen or relied on
6 any evidence suggesting that ZHP might
7 have suspected nitrosamines in valsartan
8 API earlier than June 6, 2018?
9 A. No documentation to that
10 effect. But when one is doing research
11 and development, I don't have any
12 visibility to exactly what they knew as
13 of what specific date.
14 All I know is what they have
15 represented to FDA. And I'll take that
16 as a statement of truth.
17 Q. Should Teva take as a
18 statement of truth everything its API
19 supplier, such as ZHP, say about the
20 product?
21 MR. HARKINS: Object to
22 form. Scope.
23 THE WITNESS: Respectfully,
24 I said I took that as a statement

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1 of truth, that ZHP represented a
2 truthful statement that was being
3 made to FDA.
4 And in particular, in the
5 fact that FDA was working with
6 ZHP, I'm sure that they would be
7 able to attest -- or evaluate the
8 veracity of what it was that ZHP
9 stated in their information
10 request.
11 I, just as an outside
12 observer reading this document,
13 take it on its face that it's
14 truthful, because it is a
15 representation that they made to
16 FDA, and it is the obligation of
17 those who manufacture drug product
18 and drug substances to be truthful
19 with FDA.
20 BY MR. STANOCH:
21 Q. And is it incumbent on a
22 finished dose drug manufacturer such as
23 Teva to have quality processes in place
24 to assure that its API suppliers are

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1 being truthful with Teva?
2 MR. HARKINS: Vague. Scope.
3 THE WITNESS: I don't have
4 visibility at this moment to all
5 documents that Teva used to
6 support their impression of
7 veracity of representations made
8 to them by ZHP.
9 But this is something that I
10 really can't -- cannot comment on,
11 beyond what representations there
12 was that ZHP made to FDA.
13 And I believe that Teva
14 relies on representations made by
15 ZHP to FDA every bit as much as I
16 would.
17 BY MR. STANOCH:
18 Q. And does Teva rely on the
19 FDA to make sure that Teva's own API
20 suppliers are complying with good
21 manufacturing practices?
22 MR. HARKINS: Form. Scope.
23 THE WITNESS: FDA, excuse
24 me. Teva remains abreast of

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1 findings that FDA has made at
2 their suppliers.
3 And these observations are
4 those which appear in 483. And at
5 some point, should they have
6 access to it, as I even had access
7 to some of these in the
8 preparation of this report, the
9 establishment inspection reports.
10 BY MR. STANOCH:
11 Q. You don't know how Teva
12 remains abreast of findings of the FDA
13 for its suppliers. You don't opine on
14 that in your report, do you?
15 A. I don't make a statement
16 specific to that. But everything that I
17 have written in the report and have
18 referred to in the report involve
19 communications that Teva has had with FDA
20 in the course of the valsartan recall,
21 for instance.
22 The presence of NDMA as was
23 communicated by ZHP to Teva was in part
24 on a consequence of involvement of not

<p style="text-align: right;">Page 154</p> <p>1 only the ZHP customer, who was the -- 2 whose API was being studied, but also the 3 fact that FDA were, to my understanding, 4 involved in the knowledge of the 5 investigation that proceeded with respect 6 to NDMA. 7 So I believe communications 8 from FDA that are made by those who 9 interact with them are informative. And 10 if I was Teva, I would find those to be 11 very informative. 12 Q. Nowhere in your report do 13 you analyze any policy, practice, or 14 procedure at Teva for monitoring findings 15 of the FDA for Teva's suppliers, do you? 16 A. I don't know if that's one 17 that is covered in one of the SOPs that 18 was cited. If I could just refer -- it 19 was Paragraph 84, I think you referred 20 to. I'm going to see if there's an SOP 21 here that may -- but without having it in 22 front of me, I can't say for sure. 23 But I would expect something 24 like that would possibly be referred to</p>	<p style="text-align: right;">Page 156</p> <p>1 inform -- yeah, here we go. I believe we 2 are talking -- it's at Paragraph 110, on 3 Page 28. 4 I mention that since 2015 5 Teva, by way of Actavis, had in place the 6 quality agreement for active 7 pharmaceutical ingredients dated 8 3/24/2016, and entered into with ZHP, 9 Section 7.1 and 7.2 are a part of this 10 signed agreement, which reads as follows: 11 7.1, "Zhejiang Huahai shall 12 inform Actavis within" -- and I'm 13 saying -- is lacking a word here -- 14 "within of any regulatory inspection that 15 relates to the manufacture of any API 16 supplied to Actavis, Zhejiang Huahai 17 shall provide Actavis with the 18 certificate issued after such an 19 inspection upon request." 20 7.2, "Zhejiang Huahai shall 21 promptly notify Actavis in writing on the 22 receipt of a regulatory inspection 23 report, deficiency letter, or written 24 regulatory compliance observation which</p>
<p style="text-align: right;">Page 155</p> <p>1 in the risk management SOP, the out of 2 specification SOP, product complaint SOP. 3 Predominately those three 4 SOPs I would expect might have some 5 procedural narratives that would pertain 6 to information that Teva should know. 7 Q. You are speculating right 8 now, right? 9 A. I'm not recalling. I'm 10 saying if you'd like to go to those SOPs, 11 we could look at those SOPs and to see to 12 what degree they do. And we can read 13 from them together. 14 Q. You're not offering any 15 opinion in your report, are you, sir, 16 that Teva had policies, procedures, and 17 practices in place to assure -- that 18 monitored FDA actions as to Teva's API 19 suppliers, are you? 20 A. Okay. Let me speak 21 specifically to ZHP. 22 I believe I have quoted from 23 the agreement which was in place with 24 ZHP, which causes them to be obligated to</p>	<p style="text-align: right;">Page 157</p> <p>1 contains any significant adverse finding 2 that relates to API or the facilities 3 used to produce, test, or warehouse the 4 API sold and shipped to Actavis which 5 might impact the quality of the API 6 intended to be shipped to Actavis and/or 7 potentially affecting the ability of 8 Zhejiang Huahai to produce or ship the 9 API to Actavis, such as FDA Form 483, or 10 a warning letter received from any 11 applicable regulatory authority or 12 suspension/withdrawal of one or more 13 CDPs." 14 What this is telling me is 15 they had this agreement in place with ZHP 16 in -- as far back as 2016. 17 You'll note that the 18 agreement was structured in the context 19 of Actavis, which as an agreement didn't 20 have to be changed in Teva's case and for 21 their purposes to say anything different 22 than it does say here. 23 And that the obligation 24 exists that ZHP is expected to inform</p>

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1 Teva of any inspections and outcomes that
2 a health authority has at their site.
3 Q. Sir, the agreement that you
4 fortuitously just read without being
5 asked to do so, that speaks to ZHP's
6 obligation to inform Teva, correct?
7 A. Correct.
8 MR. HARKINS: Object to the
9 colloquy. It's directly
10 responsive.
11 BY MR. STANOCH:
12 Q. You are not offering any
13 opinion in your report, sir, that Teva
14 had policies or procedures or SOPs in
15 place to ensure that Teva monitored FDA
16 actions as to Teva's API suppliers, are
17 you?
18 A. There is an SOP which
19 required Teva to have quality agreements
20 in place and the substance of that SOP
21 can be reviewed.
22 Q. We'll get to that, because
23 certainly, Teva did not have a quality
24 agreement in place with Mylan for

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1 valsartan API, did it?
2 A. It did not.
3 Q. Right. So under that same
4 SOP you just said that required quality
5 agreements, Teva wasn't following that at
6 least with respect to Mylan, right?
7 A. Not in the context of Mylan,
8 no.
9 Q. Right. And so that would be
10 an instance in which Teva was not
11 following an SOP that it had in place for
12 quality, correct?
13 A. It did not have a quality
14 agreement in place. An SOP specified
15 that a quality agreement would need to be
16 in place. They did not follow it in this
17 context.
18 That being said, not having
19 a quality agreement in place with Mylan
20 did not stand in the way of Teva being
21 able to interact with Mylan freely with
22 regard to questions that arose and that
23 pertained to cGMP issues or scheduling of
24 audits by Teva of Mylan's facilities.

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1 Q. We'll certainly get to the
2 Mylan situation a little more. But let's
3 go back to what ZHP should have told Teva
4 about valsartan API.
5 So is it your belief, sir,
6 that under the quality agreement between
7 ZHP and Actavis, which Teva inherited,
8 that ZHP should have informed Teva about
9 any suspected impurities in the valsartan
10 API?
11 MR. HARKINS: Object to
12 form. Vague.
13 THE WITNESS: Not in all
14 circumstances.
15 MR. STANOCH: Stand by.
16 BY MR. STANOCH:
17 Q. In fact, the agreement that
18 you quoted and as you indicate in your
19 report, it's actually illegible about the
20 time within which ZHP shall inform
21 Actavis about a regulatory inspection,
22 right?
23 A. You used a word there that
24 was garbled. Could you repeat the

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1 question again, please?
2 Q. In the quality agreement
3 between ZHP and Actavis that you quote in
4 your report, you yourself indicate that
5 the agreement has some sort of
6 typographical error about the time frame
7 within which ZHP shall inform Actavis of
8 regulatory inspections, right?
9 A. What the typo is that's in
10 the agreement here is they've inserted
11 the word "within." And I just reproduced
12 that accurately as was residing in the
13 agreement.
14 But if one was to read that
15 cleanly, it would be, "Zhejiang Huahai
16 shall inform Actavis of any regulatory
17 inspections that relate to the
18 manufacture," and so forth here as I said
19 before.
20 But 7.2, I know you thought
21 this was a labored reading of this. But
22 it's important to know that 7.2 is very
23 clear to say that Zhejiang Huahai shall
24 promptly notify Actavis in writing. It

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1 does not, you know, specify what promptly
2 necessarily is in terms of days or weeks
3 or months or anything like that, how
4 promptly is interpreted.
5 But from my experience in
6 reviewing such quality agreements,
7 promptly means right away. And that, I
8 believe, is probably how this was
9 expected to be interpreted as well. And
10 that would be the expectation that Teva
11 had with ZHP.
12 Q. Quantify promptly for me
13 based on your experience. What do you
14 mean by right away?
15 A. Promptly would be some time
16 at such point in time that they have
17 received their 483 report from -- from
18 FDA specifically, or at whatever the time
19 a report was produced from the health
20 authority, because that forms a basis to
21 inform a customer of the outcome of a
22 regulatory visit.
23 So it would be the most
24 meaningful information point in time to

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1 which that would happen.
2 And the firm typically has
3 15 days within to which to respond to
4 observations that are made in the 483.
5 So if you're going to be
6 communicating this kind of thing, it is
7 certainly within the ability of ZHP to
8 say oh, by the way, Teva, FDA stopped by.
9 We're still going over what the number of
10 observations are and the nature of
11 observations, such as they are. We
12 haven't settled exactly on what those
13 are, because we're still preparing
14 responses to them.
15 So what the outcome of that
16 inspection is, is still unknown at this
17 time. So the firm could communicate that
18 to Teva. ZHP could communicate that to
19 Teva in this instance and be considered
20 prompt, or they could potentially wait
21 until they have all the facts, and
22 certainly within 15 days there is
23 considered to be a reasonable amount of
24 time and -- where one actually has

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1 meaningful information with respect to
2 the inspection.
3 Q. And you're aware, are you
4 not, right, that the FDA inspected ZHP in
5 May of 2017, right?
6 A. I'm aware of that, yes.
7 Q. You are aware that that
8 inspection was not reported by ZHP to
9 Teva until quite some time after,
10 correct?
11 A. Correct.
12 Q. In fact, I think it was --
13 and you reference to your report -- a
14 Teva procurement officer stumbled upon
15 the existence of the May 2017 inspection
16 from a Bloomberg article, correct?
17 A. Correct.
18 Q. All right.
19 MR. STANOCH: I'll mark as
20 Exhibit 4.
21 (Document marked for
22 identification as Exhibit
23 Anderson-4.)
24 BY MR. STANOCH:

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1 Q. Tell me when you can see it,
2 sir.
3 MR. HARKINS: Refresh the
4 DropBox.
5 THE WITNESS: One moment,
6 please.
7 BY MR. STANOCH:
8 Q. Of course.
9 A. Loading Exhibit 4. I'm
10 there.
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

<p>Page 166</p> <p>[REDACTED]</p>	<p>Page 168</p> <p>[REDACTED]</p>
<p>Page 167</p> <p>[REDACTED]</p>	<p>Page 169</p> <p>[REDACTED]</p>

Page 170

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 non-specific requirements of our clients.

19 But what did Teva consider

20 prompt in this case, I can't speak to.

21 Q. Are you saying it's

22 reasonable for Teva to receive

23 notification from ZHP over a year after

24 the FDA conducted an inspection of ZHP?

MR. HARKINS: Object to

form. Scope.

THE WITNESS: You asked what

I did with respect to other

customers and what my experience

was with them. I have no

experience with Teva in this

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1 matter.

2 So I don't know what Teva

3 would consider to be the full and

4 complete definition of prompt.

5 You asked me earlier what

6 was it in my experience. I gave

7 you what was in my experience.

8 I do not have what is Teva's

9 experience or how they would

10 interpret this.

11 BY MR. STANOCH:

12 Q. Based on your experience,

13 understanding that it does not relate to

14 any work that you've ever done with Teva,

15 you would agree that ZHP did not promptly

16 notify Teva about the FDA's May 2017

17 inspection, correct?

18 MR. HARKINS: Object to

19 form. Scope.

20 THE WITNESS: I spoke to the

21 experience that I had with my own

22 clients, not experience that

23 anyone -- that Teva had with its

24 own suppliers or how they

Page 172

1 interpreted prompt in this case.

2 That's all I'm saying.

3 BY MR. STANOCH:

4 Q. Based on your experience

5 then, outside of ZHP and Teva, would you

6 advise a paying client of yours that it's

7 okay for the API supplier to wait over a

8 year to inform them about an FDA

9 inspection?

10 MR. HARKINS: Object to

11 form. Scope. Speculation. You

12 can answer.

13 THE WITNESS: Again, that is

14 speculative and far too general a

15 consideration here.

16 I have worked with other

17 clients, other than Teva. So what

18 Teva's interpretation of what

19 their agreement with ZHP is, I

20 would leave it up to Teva to

21 comment on. I'm not here to

22 comment on that.

23 BY MR. STANOCH:

24 Q. Have you ever advised any

Page 173

1 client of yours that it's okay to find

2 out about a regulatory inspection over a

3 year after it occurs at an API supplier?

4 MR. HARKINS: Object to form

5 scope. Speculation.

6 THE WITNESS: I do not

7 recall a circumstance where that

8 hypothetical has presented itself.

9 BY MR. STANOCH:

10 Q. You can't recall any example

11 in your decades of regulatory experience

12 in which an API supplier waited over a

13 year to tell the finished dose customer

14 about an FDA regulatory inspection; is

15 that right?

16 A. I have not encountered a

17 similar situation with the hundreds of

18 audits of API suppliers and product

19 manufacturers that I have conducted,

20 worldwide.

21 Q. Could you identify for me

22 any Teva SOP that was in place at the

23 time that should have required Teva to

24 follow up on whether the FDA conducted an

Page 174

1 inspection of ZHP in 2017?

2 MR. HARKINS: Object to

3 form. Vague.

4 THE WITNESS: Very vague in

5 the sense that I have not

6 memorized the content of SOPs and

7 would know immediately which SOP

8 contained that information.

9 We could go through the body

10 of SOPs one by one, I suppose, and

11 see where that appears.

12 BY MR. STANOCH:

13 Q. Well, you know, which SOPs

14 are you talking about? The ones that you

15 relied on in your report, or the bunch of

16 ones that you're citing in your materials

17 considered?

18 A. It could be something

19 possibly that is found in either. It's

20 not something that I have immediate

21 knowledge of. As I said, we could always

22 go through the SOPs and find out where

23 that exists.

24 Q. We can agree, though, I

Page 175

1 believe, Mr. Anderson, that you're not

2 opining on whether or not Teva had an SOP

3 in place that would have required it to

4 monitor FDA actions at API suppliers such

5 as ZHP, correct?

6 A. I am not certain which SOP

7 governs that particular operation.

8 Q. You can't even tell me

9 sitting here whether there is an SOP that

10 governed that, correct?

11 MR. HARKINS: Form. Scope.

12 You can answer.

13 THE WITNESS: Again, the

14 content of SOPs that -- such they

15 are at Teva, is not something that

16 I familiarized myself with deeply,

17 nor do I quote from any of the

18 SOPs, with the exception on, I

19 believe, one SOP that I thought

20 was necessary to make a point.

21 But I obviously don't recall

22 which SOP this particular

23 monitoring requirement is

24 detailed.

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1 BY MR. STANOCH:

2 Q. All right. Sitting here

3 now, can you identify for me any Teva SOP

4 that would have spoke to Teva's

5 obligation to monitor regulatory activity

6 at one of Teva's API suppliers?

7 MR. HARKINS: Form. Scope.

8 THE WITNESS: Again, I have

9 no immediate recall of which SOP

10 governs that function.

11 MR. HARKINS: Dave, I don't

12 know if you're switching to a new

13 thing. We've been going over an

14 hour. And I think we'll want to

15 recheck on what we're doing for a

16 lunch arrangement. So probably a

17 short break here when it's ready.

18 MR. STANOCH: Steve, let's

19 go a little longer on this

20 subject, and then we can take a

21 break depending on Mr. Anderson's

22 stamina.

23 BY MR. STANOCH:

24 Q. Mr. Anderson, you talk a

Page 177

1 little bit more about this particular

2 e-mail exchange, I believe, in your

3 report around Paragraphs 112 through 117.

4 A. I do.

5 Q. Can you recall any instance

6 in your decades of experience in which a

7 finished drug product manufacturer had to

8 learn about an FDA inspection at one of

9 its API suppliers over a year later

10 through a public news article?

11 A. I have had no example of

12 that in my many years of experience

13 consulting.

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 [REDACTED]

20 [REDACTED]

21 [REDACTED]

22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

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[REDACTED]

Page 180

[REDACTED]

3 Q. You're not an expert in
4 reading documents, are you, Mr. Anderson?
5 MR. HARKINS: Object to
6 form.
7 You can answer, I guess.
8 THE WITNESS: I consider
9 myself to be an expert reader.
10 BY MR. STANOCH:
[REDACTED]

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[REDACTED]

Page 181

[REDACTED]

Page 182

[REDACTED]

Page 184

[REDACTED]

Page 183

[REDACTED]

Page 185

[REDACTED]

Page 186

[REDACTED]

Page 188

[REDACTED]

Page 187

[REDACTED]

Page 189

[REDACTED]

Page 190

[REDACTED]

Page 192

[REDACTED]

10 BY MR. STANOCH:

11 Q. And you said that you didn't

12 undertake any analysis to determine if

13 anyone at Teva learned about the May 2017

14 inspection prior to August of 2018,

15 right?

16 A. This is the only document

17 that I was supplied with.

18 Q. Right. Had Teva learned of

19 the May 2017 FDA inspection of ZHP

20 sooner, it could have had conversations

21 with ZHP about those inspection

22 observations at an earlier time, right?

23 MR. HARKINS: Form. Vague.

24 Speculation.

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[REDACTED]

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1 THE WITNESS: That is

2 speculation. And what the nature

3 of those conversations are and the

4 timing as to those conversations,

5 it certainly depends on when those

6 happen.

7 BY MR. STANOCH:

[REDACTED]

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[REDACTED]

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1 - - -
2 THE VIDEOGRAPHER: The time
3 right now is 2:11 p.m. We're back
4 on the record.
5 - - -
6 CONTINUED EXAMINATION
7 - - -
8 BY MR. STANOCH:
9 Q. Welcome back, Mr. Anderson.
10 Other than Mr. Harkins, did
11 you talk or communicate with anybody else
12 during the lunch break?
13 A. No, I did not.
14 Q. Did you look at any
15 documents during the break?
16 A. No.
17 Q. What's your understanding of
18 some of the root causes identified by the
19 FDA eventually for NDMA and NDEA?
20 A. I believe, as I recall from
21 the way that FDA has identified potential
22 root causes, had to do with formation of
23 nitrous acid during a reaction using the
24 new catalysts and new DMF solvents and

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[REDACTED]

12 MR. STANOCH: Mr. Anderson,
13 now is a good time for a lunch
14 break. I'm happy to do it or we
15 can keep going. You let me know.
16 THE WITNESS: Let's break
17 for lunch at 1 o'clock.
18 MR. STANOCH: Okay.
19 THE VIDEOGRAPHER: The time
20 right now is 12:57 p.m. We are
21 off the record.
22 - - -
23 (Whereupon a luncheon recess
24 was taken.)

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1 the side reactions that resulted from
2 that which were not heretofore detected
3 was a reason for having this process
4 impurity manifest itself, at least
5 certainly by the ZHP process.
6 The Mylan process is not the
7 same as ZHP's process. And the presence
8 of NDEA, which I understand is at a
9 concentration far less than NDMA, is
10 present in or was found in the Mylan
11 process to be a consequence of a
12 contamination entered into the API by use
13 of recycled solvent that are used in
14 manufacturing, or possibly water too that
15 was used in the manufacturing process.
16 Q. Thank you.
17 And that first potential
18 root cause with respect to the ZHP
19 valsartan API, you understand generally
20 it had to do with the nitrous acid and
21 the quenching process during the
22 manufacture?
23 A. Yes. Reaction quenching
24 process, yes, correct.

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1 Q. And I think we testified --
2 we talked about this a little bit before
3 lunch, that, you know, you cite in your
4 report that it was Novartis telling ZHP
5 about NDMA in the valsartan API in early
6 June of 2018, right?
7 A. Correct.
8 Q. And you're not aware of
9 whether or not ZHP knew about the
10 potential for nitrosamines in valsartan
11 API prior to June 2018?
12 A. I'm not aware of what ZHP
13 knew to that point. All I know is what
14 they attest to in the information request
15 response to FDA.
16 MR. STANOCH: I'm going to
17 mark the next exhibit. Exhibit 5.
18 (Document marked for
19 identification as Exhibit
20 Anderson-5.)
21 BY MR. STANOCH:
[REDACTED]

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[REDACTED]

Page 200

[REDACTED]

Page 201

[REDACTED]

Page 202

[REDACTED]

Page 204

[REDACTED]

Page 203

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Page 224

[REDACTED]

Page 223

[REDACTED]

Page 225

[REDACTED]

Page 226

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 BY MR. STANOCH:
7 Q. You're saying until the FDA
8 figured it out in December of 2018, all
9 the other manufacturers, even if they
10 found out about it, didn't have to do
11 anything?
12 MR. HARKINS: Object to
13 form. Misstates testimony.
14 Scope.
15 THE WITNESS: Well, they
16 certainly took it upon themselves
17 to pay attention to the issue. I
18 don't know what they mean by pay
19 attention to the issue. But it
20 certainly wasn't ignored, the
21 issue, okay.
22 So I don't know what level
23 of attention they were giving to
24 this, though they were put on

Page 227

1 notice to do so in 2017.
2 And again, I don't know at
3 what point ZHP began to speak with
4 FDA concerning the presence of
5 NDMA, NDEA, or any of the levels
6 that FDA might at some point adopt
7 for limiting substances in API.
8 But there were no limits
9 established for API during the
10 time -- during the time that Teva
11 was marketing their valsartan
12 products.
13 BY MR. STANOCH:
14 Q. When you say without --
15 there were no limits, that means the
16 limit is zero; isn't that right?
17 MR. HARKINS: Object to
18 form. Scope.
19 THE WITNESS: I think there
20 are no limits that are present.
21 It's not that limit is zero.
22 When you said limit is limit
23 is zero, that's coming with an
24 expectation that no, absolutely

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1 zero, NDMA, NDEA may be present in
2 a drug product.
3 FDA never said that. Even
4 today FDA never said that.
5 So when you use that
6 terminology, in saying zero in
7 this context, I think it's not --
8 it's not operative.
9 BY MR. STANOCH:
10 Q. Was it your testimony a
11 moment ago that the FDA never said that
12 zero was the appropriate amount of
13 nitrosamines in sartan API?
14 A. As a specification, as they
15 have stated it, they never said zero.
16 Q. As a specification. That's
17 how you're qualifying the answer?
18 A. Yes, because that is the
19 regulatory metric that is used and how
20 enforcement is understood.
21 Q. And you understand, I take
22 it then, that the FDA has said in the
23 past that a drug substance should not
24 contain any nitrosamines because it's

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1 controlled. Do you recall that?
2 A. What I recall is that they
3 were at that time that you're referring
4 to -- this document I believe was
5 something that was issued in 2019.
6 You're talking about the
7 general advice, I believe, where FDA
8 essentially, in a perfect world, one
9 would not want to have impurities of --
10 really of any kind that are in a drug
11 substance.
12 Okay. You realize that is
13 not the real world and that impurities
14 are there. And in fact, FDA established
15 limits for the impurities specific to
16 NDMA and NDEA as far back at that point
17 as December of 2018.
18 So it is a -- it is a time
19 where FDA is -- is writing even as
20 they're thinking.
21 They are formulating, you
22 know, the direction that something like
23 this is going to go, is ultimately going
24 to go.

<p style="text-align: right;">Page 230</p> <p>1 This is a time that they 2 have not yet developed what became the 3 GC-MS assay method, which is now what is 4 operative for API manufacturers in order 5 to determine what level, if any, of NDMA 6 or NDEA are present in drug substances. 7 And that didn't come around until roughly 8 2020. 9 Q. Are you aware of any risk 10 assessment that Teva conducted of 11 valsartan API for genotoxic impurities 12 prior to June of 2018? 13 A. I do not have any -- I did 14 not review any risk assessments that 15 mentioned genotoxic impurities. 16 Q. Are you aware of any risk 17 assessment Teva conducted of its own 18 valsartan finished dose product prior to 19 June of 2018? 20 A. I did not review any 21 documents pertaining to genotoxicity and 22 discussions that Teva had as a product 23 manufacturer about it. 24 Q. Did you review any Teva SOPs</p>	<p style="text-align: right;">Page 232</p> <p>1 time the risk assessment SOP is dated. I 2 know what I requested to look is what the 3 current version of that is. I don't know 4 what the version history of it is. 5 Q. You can't say sitting here 6 what the Teva SOP for risk assessment was 7 during the 2012 to 2018 time period? 8 MR. HARKINS: Form. Scope. 9 THE WITNESS: I don't have 10 an immediate recollection of what 11 was in the risk assessment SOP or 12 what its revision history is. 13 BY MR. STANOCH: 14 Q. And the risk assessment SOP 15 that you cite in your report, the current 16 version, that's as it relates to an 17 assessment in the summer of 2018, right? 18 A. The SOP that I referred to 19 and the purposes that I referred to it 20 was to, again, compare against John 21 Quick's mention of risk assessment SOPs 22 as being meaningful to governing quality 23 systems. 24 I did not read the SOP to</p>
<p style="text-align: right;">Page 231</p> <p>1 regarding when it should conduct risk 2 assessments and what they should entail 3 for API or finished dose product prior to 4 June 2018? 5 MR. HARKINS: Object to 6 form. Scope. 7 THE WITNESS: Could you 8 rephrase that question, please? 9 BY MR. STANOCH: 10 Q. Did you review any Teva SOPs 11 concerning Teva's conducting risk 12 assessments for finished dose product or 13 API? 14 MR. HARKINS: Same 15 objection. 16 THE WITNESS: I read the 17 risk assessments SOP that is based 18 on the ICH Q9. I did just do a 19 cursory read through it. 20 BY MR. STANOCH: 21 Q. That's the one that was put 22 into effect after the recalls began in 23 the summer of 2018, right? 24 A. I don't know exactly what</p>	<p style="text-align: right;">Page 233</p> <p>1 any amount of depth. I gave it a cursory 2 review and confirmed that, in fact, one 3 existed. That's the only thing that I 4 did with respect to that SOP. 5 Q. Do you know if the Teva SOP 6 on risk assessments related to conducting 7 analyses of API before it is purchased? 8 A. Again, what is contained in 9 that SOP is not something that I have an 10 immediate memory about. It certainly can 11 be brought up and we can read the SOP 12 from front to back and learn what is in 13 it. 14 Q. We had talked about 15 June 2018 and NDMA, and then I think you 16 write, starting in Paragraph 100, about 17 Teva's awareness of NDEA. 18 A. I'm going to that paragraph 19 right now. 20 MR. HARKINS: Which 21 paragraph? 22 THE WITNESS: 100, I believe 23 he mentioned. 24 Okay. I am at Paragraph</p>

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1 100.
 2 BY MR. STANOCH:
 3 Q. And here you write in part
 4 that Teva first became aware of the
 5 potential of a different impurity, NDEA
 6 in valsartan API purchased from Mylan,
 7 India, by way of a notification from
 8 Swissmedic on November 5, 2018. And then
 9 you continue there, right?
 10 A. That is correct.
 11 Q. Okay. So your belief is
 12 that Teva first became aware of the
 13 potential for NDEA on November 5, 2018?
 14 A. In Mylan's API, yes.
 15 Q. Well, you're qualifying
 16 there with Mylan's API. When did Teva
 17 first become aware of the potential for
 18 NDEA in valsartan API, period?
 19 MR. HARKINS: Form. Scope.
 20 THE WITNESS: I understand
 21 that Teva was in the process of
 22 doing some significant
 23 investigation with respect to
 24 their valsartan API, first

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1 starting with respect to NDMA.
 2 But also expanding into the
 3 possibility that the nitrosamine
 4 NDEA and possibly others might
 5 also be present.
 6 So I believe this was all
 7 part of something that Teva was
 8 investigating at the time, but
 9 learned conclusively by way of a
 10 field alert here that involved
 11 Swissmedic, who reported that they
 12 found NDEA in Mylan API.
 13 BY MR. STANOCH:
 14 Q. So you agree that Teva was
 15 aware of the potential for NDEA to form
 16 in valsartan API prior to November 5th,
 17 2018, correct?
 18 MR. HARKINS: Form.
 19 Misstates testimony.
 20 THE WITNESS: I believe that
 21 they were studying the possibility
 22 of its formation.
 23 I do not know whether they
 24 determined that there was anything

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1 as a matter of an emergence of
 2 NDEA as a process impurity with
 3 their synthetic process.
 4 Here, again, Mylan's
 5 synthetic process is different
 6 from ZHP's. And Mylan in fact
 7 related to Mylan -- excuse me.
 8 Mylan related to Teva early
 9 on in its investigative process,
 10 that its method of synthesis was
 11 different from ZHP's.
 12 So an inquiry was made of
 13 Mylan, do you suspect that NDMA is
 14 part of your process, as we have
 15 found it to be elsewhere.
 16 Mylan says that is not our
 17 process. And on that basis, Teva
 18 did not at that time suspect that
 19 NDMA would be part of Mylan's
 20 process.
 21 And I don't know that I have
 22 read anything to suggest that I
 23 recall that NDMA is part of
 24 Mylan's process. Although it was

Page 237

1 revealed that NDEA was associated
 2 with Mylan's process.
 3 BY MR. STANOCH:
 4 Q. Right. And you're saying
 5 that was not revealed, about the NDEA,
 6 until Swissmedic affirmatively told Teva
 7 that Teva's own product contained NDEA on
 8 November 5th, 2018?
 9 A. By way of that notification
 10 from Swissmedic, yes, that Mylan API was
 11 found to contain NDEA, as I wrote down.
 12 Q. From your knowledge, did
 13 Teva ever test any of its own valsartan
 14 or the valsartan API that it was buying
 15 from Mylan, for NDEA prior to
 16 November 5th, 2018?
 17 MR. HARKINS: Object to
 18 form. Scope.
 19 THE WITNESS: I have no
 20 knowledge of what kind of testing
 21 was being done specifically on
 22 Mylan's API.
 23 BY MR. STANOCH:
 24 Q. From a cGMP perspective,

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1 would it be appropriate for a finished
2 dose manufacturer on notice of the
3 potential for NDEA, to test its valsartan
4 and valsartan API for that substance?
5 MR. HARKINS: Form. Vague.
6 Speculation.
7 THE WITNESS: What Teva had
8 to inform themselves were
9 certificates of analysis from
10 their suppliers that showed
11 whether they conformed with the
12 specifications that were appended
13 to their purchasing of that API,
14 and whether in fact those
15 specifications were the same as
16 the ones that were approved for
17 the application.
18 Now, unless there was a
19 notification that any one of those
20 specifications were offended, Teva
21 was of the reasonable belief that
22 the drug substance, based on how
23 it was represented as conforming
24 with the specification, was

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1 something that was remaining
2 within cGMP compliance.
3 BY MR. STANOCH:
4 Q. Well, let's unpack some of
5 that. Well, first of all, certificates
6 of analysis that you reference, you told
7 us this morning that you don't rely on
8 specific ones in your opinions in your
9 report, right?
10 MR. HARKINS: Object to
11 form. Misstates testimony.
12 THE WITNESS: I don't
13 reference them as footnotes in my
14 report, although they are
15 documents considered.
16 BY MR. STANOCH:
17 Q. Right. And again, how am I
18 supposed to replicate your analysis,
19 Mr. Anderson, and know whether something
20 in your materials considered was or was
21 not actually relied upon for the body or
22 footnotes of your report?
23 MR. HARKINS: Form. Asked
24 and answered.

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1 THE WITNESS: You're welcome
2 to review any one of those
3 certificates of analysis and
4 inform yourself, even as I was.
5 BY MR. STANOCH:
6 Q. That's not my question, sir.
7 How am I supposed to know
8 from reading your report, right, which
9 certificates of analysis you're relying
10 on for your opinions, not that you saw
11 and put aside, that you're relying on for
12 your opinions?
13 How can I know that?
14 MR. HARKINS: Form. Asked
15 and answered.
16 THE WITNESS: There was no
17 specification for NDMA and NDEA at
18 the time that any of those
19 certificates of analysis were
20 generated; hence, the requirement
21 in a regulatory sense was not
22 there to report presence of NDMA
23 or NDEA in concentrations as
24 measured against the specification

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1 which did not exist.
2 BY MR. STANOCH:
3 Q. I'm going to ask my question
4 again about the certificates that you
5 relied on, sir.
6 How am I supposed to know
7 reading from your report which
8 certificates of analysis you're relying
9 on for your opinions?
10 MR. HARKINS: Objection to
11 form. Asked and answered.
12 You can answer again.
13 THE WITNESS: Again, you're
14 welcome to go through me -- with
15 me, each one of those certificates
16 of analysis to determine whether
17 there was an NDMA or NDEA value
18 that was reported to them or by
19 specification was required to be
20 reported to them. And you will
21 find that there is no such
22 specification or report in any one
23 of them.
24 BY MR. STANOCH:

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1 Q. You understand, sir, that
2 you're supposed to identify the materials
3 that you relied upon in forming your
4 opinions. Do you understand that?
5 MR. HARKINS: Dave, he told
6 you that he reviewed all of them
7 and did not find it necessary to
8 cite any of them in his report.
9 And he's explained the
10 specific reason that he didn't
11 feel it was necessary to cite any
12 of them, because he did not find
13 the information that he's
14 described five times in a row now,
15 in any of those certificates of
16 analysis.
17 You can answer again.
18 THE WITNESS: Again, the
19 specifications for NDMA and NDEA
20 did not exist until December 2018.
21 The certificates of analysis
22 that I reviewed predated that
23 specification; hence, it was no
24 surprise to me, as I reviewed

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1 them, that there was no presence
2 of data that pertained to NDMA or
3 NDEA qualification or a
4 specification against which they
5 were evaluated or anything having
6 to do with the regulatory
7 submission that required any such
8 evaluation in order to remain
9 within cGMP compliance.
10 BY MR. STANOCH:
11 Q. Sir, you understand you're
12 supposed to identify the materials that
13 you rely upon in forming your opinions.
14 Do you understand that?
15 A. I understand that.
16 Q. Right. And you've told me
17 in the morning that you rely in your
18 opinions on the materials that are in
19 cited the body or the footnotes of your
20 report; is that right?
21 A. That is correct.
22 Q. So the only way I know what
23 you relied on is if it's cited in a
24 paragraph or in a footnote, correct?

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1 MR. HARKINS: Object to
2 form. Misstates the testimony.
3 THE WITNESS: And there is
4 also this exhibit which has the
5 list of materials considered so
6 one is able to do as you have done
7 and ask me what those list of
8 materials were, and they happen to
9 include certificates of analysis
10 that are named that don't happen
11 to have specifications or data
12 pertaining to NDMA and NDEA,
13 unsurprisingly.
14 BY MR. STANOCH:
15 Q. So now you're telling me all
16 the certificates of analysis in your
17 materials considered exhibit were things
18 that you relied on now. Is that what
19 you're saying now?
20 A. I'm saying that I looked at
21 those, but I didn't have to make a
22 statement regarding numerical
23 specifications and conformance therewith
24 until FDA issued its specification

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1 guidance in 2018, December of 2018.
2 Q. In terms of these
3 specifications you keep saying, if a
4 manufacturer is put on notice of the
5 potential for an impurity in their
6 product, that's not on the specification,
7 is it incumbent on them to test and
8 evaluate for that or just ignore that?
9 MR. HARKINS: Form. Scope.
10 THE WITNESS: Again, to
11 remain within cGMP compliance,
12 there is the expectation of FDA
13 that you make products in
14 accordance with the production as
15 it is described in the ANDA using
16 the API of the quality that is
17 approved to be used in that
18 application and to conform to
19 those specifications in order to
20 continue marketing the product.
21 NDMA and NDEA were not part
22 of API specifications to which
23 Teva's products were required to
24 conform because the specifications

<p>Page 246</p> <p>1 did not exist when valsartan made 2 by Teva was being marketed. 3 At the time the 4 specifications went in, there was 5 no valsartan product being 6 marketed by Teva. 7 BY MR. STANOCH: 8 Q. So you're saying that even 9 if Teva had reason to believe that its 10 valsartan products contained NDEA, it had 11 no obligation to do anything with that 12 information if and unless the FDA changed 13 the specification? 14 MR. HARKINS: Object to 15 form. Vague. Speculation, 16 misstates testimony. Compound. 17 THE WITNESS: In order to 18 continue marketing their product, 19 it was Teva's obligation to 20 conform to approved 21 specifications. NDMA and NDEA 22 content were not governed by 23 FDA-directed specifications during 24 the time of Teva's marketing of</p>	<p>Page 248</p> <p>1 Did Teva have any obligation 2 to do anything with that information from 3 a cGMP standpoint? 4 MR. HARKINS: Form. Scope. 5 Speculation. 6 THE WITNESS: From a cGMP 7 aspect, the product that they had 8 to market had to contain API that 9 conformed to the specifications as 10 stated for reporting impurities, 11 and that threshold level was at 12 the level of 0.05 percent. 13 NDEA appears in valsartan 14 when it does at levels far below 15 0.05 percent. 16 In fact, we are talking in 17 terms of parts per million and 18 parts per billion. 19 So these types of 20 quantification and qualification, 21 per the specifications that 22 pertain to Teva's valsartan during 23 the time that it was being 24 manufactured and distributed and</p>
<p>Page 247</p> <p>1 valsartan. 2 BY MR. STANOCH: 3 Q. Did Teva have any obligation 4 to do anything if it had reason to 5 believe its valsartan products might 6 contain NDEA? 7 MR. HARKINS: Form. Scope, 8 vague. 9 THE WITNESS: Teva had the 10 obligation to conform with 11 specifications in their 12 application. 13 BY MR. STANOCH: 14 Q. Anything else? 15 MR. HARKINS: Objection. 16 THE WITNESS: In order to 17 conform to cGMP compliance, which 18 is the scope of my report, nothing 19 else. 20 BY MR. STANOCH: 21 Q. So let's take that a step 22 farther then. Let's say Teva knew that 23 its product -- its valsartan had the NDEA 24 in it.</p>	<p>Page 249</p> <p>1 marketed, Teva had to conform to 2 the approved specifications based 3 on ICH Q3A. 4 BY MR. STANOCH: 5 Q. What if some of Teva's 6 valsartan product had a thousand 7 milligrams of anthrax in it. Anthrax is 8 not in the specification, is it? 9 A. Anthrax is also, you 10 understand, an externally added 11 contaminant. It is not something that is 12 part of the valsartan process. There is 13 a difference. 14 Q. Let's say there -- tell 15 me -- tell me a very highly toxic poison 16 impurity. 17 MR. HARKINS: Dave, he 18 wasn't finished his answer. So 19 I'm going to ask you to let him to 20 complete. 21 THE WITNESS: Yes. Allow me 22 to complete. 23 Anthrax as an external 24 contaminant to the product itself</p>

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1 is exactly that. And there is law
2 that speaks to contaminations.
3 Okay.
4 Process impurities are not
5 contaminations. You must
6 distinguish that in your lexicon
7 here, because, again, what this is
8 is nitrosamine in the context of
9 ZHP, were process impurities that
10 happened from a side reaction
11 which no one anticipated, no
12 regulatory authority anticipated,
13 no other manufacturer of valsartan
14 product or API anticipated, and
15 FDA admitted caught them
16 unexpectedly.
17 Okay. So that's a process
18 impurity.
19 What you have described,
20 anthrax, is something which in its
21 substance is so completely foreign
22 to the process of either valsartan
23 API synthesis or valsartan drug
24 product manufacture, it can only

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1 be classified as a contaminant.
2 So it's a very different
3 kind of circumstance that we're
4 talking about here, as an external
5 impurity.
6 BY MR. STANOCH:
7 Q. Are you done, sir?
8 A. I'm done now.
9 Q. Very good. I wanted to make
10 sure.
11 Take another process
12 impurity that you can imagine, and say it
13 was in a thousand milligrams of it in
14 Teva's valsartan. But it's not in the
15 specification.
16 Does Teva have any
17 obligation to do anything about that?
18 MR. HARKINS: Speculation.
19 Scope. Objection.
20 THE WITNESS: Let me start
21 off by saying that the valsartan
22 products there, I don't believe,
23 were tableted with a potency of
24 valsartan higher than

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1 320 milligrams.
2 So when you're talking about
3 a thousand milligrams of some
4 external entity being found as a
5 contaminant of a product, of a
6 valsartan product, this is a very
7 obvious contamination here.
8 BY MR. STANOCH:
9 Q. Now, it's a contamination,
10 not an impurity? I don't understand,
11 sir. We are talking about process
12 impurities, right?
13 A. It is contamination, not a
14 process impurity, because that did not
15 form during the process.
16 Q. So you're telling me that
17 any process impurity that Teva might have
18 been aware of in its valsartan that was
19 not in the specification for valsartan
20 would not have to be acted on in any way
21 by Teva?
22 MR. HARKINS: Object to
23 form. Misstates the testimony.
24 THE WITNESS: That was not

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1 above a reportable level,
2 according to ICH Q3, which I have
3 stated many times.
4 BY MR. STANOCH:
5 Q. And ICH Q3, which
6 incorporates the M7 guidance, says that
7 it's incumbent on the manufacturer to
8 characterize and assess potential cohort
9 of concern impurities, such as
10 nitrosamines, and come up with a
11 potential level or control, does it not?
12 A. M7 mentions the cohort of
13 concern, if I recall correctly, not ICH
14 Q3.
15 But that taken into
16 consideration, there is a cohort of
17 concern about which manufacturers of drug
18 substances should be aware and design
19 processes to minimize.
20 And in fact, looking at your
21 Exhibit Number 5, where it says to the
22 leaders, "Please pay attention to this
23 issue, I think that's something that's
24 done in the spirit of following the

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1 guidance that M7 recommends.
2 Q. And to your knowledge, was
3 Teva ever designing any process to
4 minimize the NDEA in its valsartan
5 product prior to November 5, 2018?
6 MR. HARKINS: Object to
7 form. Scope.
8 THE WITNESS: You do
9 understand that Teva is not
10 manufacturing the API within which
11 any of the NDMA or NDEA were
12 found. This wasn't a subject of
13 product formulation or counting
14 specifications or dissolution
15 profiling or anything having to do
16 with that.
17 That's what Teva was
18 preparing and was marketing to the
19 public. It incorporated API from
20 either ZHP or from Mylan.
21 And it was Teva's obligation
22 to tablet the product for
23 marketing purposes that conforms
24 with its specifications, and it

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1 did so during the time that it was
2 marketing valsartan.
3 BY MR. STANOCH:
4 Q. You're not aware of Teva
5 ever communicating with any of its
6 valsartan API suppliers about processes
7 to minimize the NDMA or NDEA in the
8 valsartan API that Teva was purchasing,
9 correct?
10 MR. HARKINS: Objection.
11 Scope.
12 THE WITNESS: Not to my
13 knowledge during the time that
14 they were still marketing and
15 manufacturing the valsartan
16 products.
17 I do understand that there
18 were some investigations and there
19 was some dialogue that Teva
20 continued to have with the API
21 suppliers with respect to their
22 processes.
23 BY MR. STANOCH:
24 Q. Do you think it's

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1 appropriate for Teva to ignore customer
2 requests to test Teva's own valsartan
3 product for nitrosamines?
4 MR. HARKINS: Object to
5 form. Foundation. Scope.
6 THE WITNESS: I'm not aware
7 of any condition that you are
8 speaking of here, so I can't
9 really comment.
10 BY MR. STANOCH:
11 Q. Well, from the cGMP
12 perspective, is it appropriate for Teva
13 to ignore a customer request to test
14 Teva's own valsartan product for
15 nitrosamines?
16 MR. HARKINS: Form.
17 Foundation. Scope.
18 THE WITNESS: Teva handled
19 complaints. It had an SOP which
20 is part of its quality system,
21 which describes how complaints are
22 handled.
23 It is not specific to the
24 type of complaints that it might

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1 be able to field with any specific
2 context.
3 Complaints are fielded by
4 customers for any number of
5 reasons. And it is possible that
6 a customer could have complained
7 about the level of valsartan --
8 excuse me -- the NDMA, NDEA, that
9 it found to be present in the drug
10 product that Teva made.
11 BY MR. STANOCH:
12 Q. Would it be appropriate from
13 a cGMP perspective for Teva to ignore
14 such a customer request?
15 MR. HARKINS: Same
16 objection.
17 THE WITNESS: As I said,
18 there was an SOP which governs the
19 handling of complaints. And since
20 any and all complaints would be
21 ones that Teva would be
22 considering and reporting, which
23 they must do by law, it is not up
24 to Teva to ignore complaints when

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1 they come in, no matter what they
2 are.
3 BY MR. STANOCH:
4 Q. So if a customer asked Teva
5 if NDEA was in Teva's product, they
6 should report that complaint to the FDA?
7 A. Well, you're doing two
8 things here. One of them is asking a
9 question. The other one is actually
10 saying we found NDEA in the valsartan
11 tablets, and we are watching that
12 complaint. It's not making an inquiry of
13 whether Teva found NDEA or NDMA in a
14 product. That's a different thing.
15 That's not a complaint.
16 Q. So it would only be a
17 customer complaint if the customer
18 affirmatively identified the NDEA itself
19 in Teva's products?
20 MR. HARKINS: Object to
21 form. Foundation. Scope.
22 THE WITNESS: When one is
23 complaining, one is accusing.
24 So there must be a basis for

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1 what that accusation is. And if
2 the accusation has any merit, it
3 will be judged accordingly by Teva
4 with respect to its severity, its
5 frequency, and the type of
6 complaints that was being made and
7 whether there is in fact any
8 evidence that is presented by the
9 one lodging the complaint that the
10 complaint itself is valid at all.
11 BY MR. STANOCH:
12 Q. What obligations from a cGMP
13 standpoint does Teva have to investigate
14 a complaint itself?
15 A. Teva has the obligation to
16 investigate the complaint thoroughly.
17 And whatever that complaint is, the
18 definition of thoroughness is per the
19 complaint itself.
20 Q. What obligations from the
21 cGMP standpoint does Teva have to
22 investigate an inquiry as to whether
23 Teva's products contain nitrosamines?
24 A. Well, that would be a

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1 different unit. That would probably be
2 the medical information officer that
3 would be handling an inquiry that you're
4 describing here. That's not a complaint.
5 Medical affairs is a
6 department which exists to address
7 questions. But when we're talking about
8 product complaints, we're talking about
9 something that is directly related to
10 potential cGMP issues. The other one is
11 merely an inquiry about certain aspects
12 of the drug product that someone may have
13 in their possession or not.
14 Q. So if a Teva customer asked
15 Teva, "Is there nitrosamines in this
16 valsartan product you sold me?" is that a
17 complaint or an inquiry?
18 A. That's an inquiry.
19 Q. Okay. So that would go to
20 Teva medical affairs?
21 A. Right. If the --
22 Q. Did you review -- hold on.
23 I'm sorry, go ahead.
24 A. I'm sorry. If the customer

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1 comes to him, comes to Teva, and says, we
2 have detected NDMA in your drug product,
3 then that would be made part of the
4 complaint investigation to determine the
5 scope of what the complaint involved, how
6 the complaint was arrived at, what
7 evidence exists that the customer has
8 that it happened to exist at a certain
9 level, or if it exists at all.
10 The mere accusation is not
11 sufficient there for Teva to have to make
12 something actionable from a regulatory
13 standpoint apart from reporting what the
14 complaint itself is.
15 And if, after investigation,
16 they found there was no evidence for the
17 complaint, the complaint is closed.
18 Q. What, if any, steps did Teva
19 take to assure that its own valsartan
20 product did not contain NDEA prior to
21 November 5, 2018?
22 MR. HARKINS: Object to
23 form. Foundation. Scope.
24 THE WITNESS: I know that

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1 Teva was undertaking
2 investigation.
3 In fact, if I recall
4 correctly, Teva's determination
5 that NDEA may be present in
6 valsartan products was a
7 determination that they came to
8 within days of learning of this
9 from Swissmedic.
10 So it was something that
11 they were looking at at that time.
12 But, of course, they had to make
13 sure that the data they were
14 requiring was data that was
15 supportive of the possibility that
16 NDEA was present. So it was
17 something they were looking at.
18 BY MR. STANOCH:
19 Q. Was Teva aware that NDEA was
20 present in the valsartan API it was
21 purchasing from Mylan prior to
22 Swissmedic's notification of November 5,
23 2018?
24 MR. HARKINS: Object to

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1 form. Scope.
2 THE WITNESS: I know that
3 they were studying both NDMA and
4 NDEA from -- whether they were
5 looking at both Mylan's as well as
6 ZHP's, I would consider that a
7 possibility. But I don't know
8 what the scope of their
9 investigation was at that point,
10 only to say that NDEA was
11 something that was suspect as
12 possible, as might be any other
13 nitrosamines that were part of
14 that group.
15 So I think they were doing
16 kind of a broad investigation and
17 study of API suppliers, and I
18 don't know for certain, but it may
19 have come up that it was NDMA --
20 NDEA that was associated with
21 Mylan's API.
22 BY MR. STANOCH:
23 Q. How soon do you believe NDEA
24 was something that Teva suspected was

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1 possible in its valsartan products?
2 A. I would say that as they
3 were undergoing their own investigations,
4 these studies, without having an exact
5 reference, would be ones that would have
6 happened at some point in time that they
7 were notified by ZHP that NDMA was
8 present in their -- in their API.
9 I don't know exactly on what
10 date they initiated studies to look at
11 the presence of nitrosamines of other
12 kinds in all of the sources of APIs that
13 they were obtaining and where
14 nitrosamines might be possible.
15 I don't know the dates on
16 which they began their testing and
17 studies with regard to that.
18 Q. What cGMP obligations, if
19 any, did Teva have to study the presence
20 of nitrosamines of other kinds, as you
21 say, in all the sources of the valsartan
22 APIs that it was purchasing?
23 MR. HARKINS: Object to
24 form. Scope. Compound.

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1 THE WITNESS: As far as cGMP
2 investigation was concerned, one
3 is doing investigations in
4 conjunction with what approved
5 specifications are. This is what
6 cGMP is governing.
7 CGMP is not governing R&D
8 investigations.
9 BY MR. STANOCH:
10 Q. Anything else?
11 A. Nothing else.
12 MR. HARKINS: Dave, we've
13 been going over an hour. I don't
14 know if there's a spot for
15 five-minute coffee and bio break
16 whenever you're finding a good
17 spot.
18 MR. STANOCH: Yeah, let's
19 wrap this up for a few more
20 minutes and then we can do that.
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

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[REDACTED]

Page 268

[REDACTED]

Page 267

[REDACTED]

Page 269

[REDACTED]

Page 270

[REDACTED]

Page 272

[REDACTED]

Page 271

[REDACTED]

Page 273

[REDACTED]

Page 274

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

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1 26 of your report.
2 A. I'm there.
3 Q. And here, starting at
4 Paragraph 101 and then the ensuing
5 paragraphs, you're rebutting an assertion
6 by Mr. Quick about SOPs Teva had in
7 place, which you say were called upon to
8 manage the customer API supplier
9 relationships with ZHP and Mylan; is that
10 right?
11 A. That's correct.
12 Q. And we already discussed
13 that Teva did not have a quality
14 agreement in place with Mylan, right?
15 A. Correct.
16 Q. And then you go on to say,
17 well, in Paragraph 103 and 104, Teva had
18 SOPs in place to manage the customer API
19 supplier relationships anyway, right?
20 A. Correct.
21 Q. And then in 103, you
22 identify -- one, two, three, four -- six
23 CORP policies of Teva that you say
24 governs the customer API supplier

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1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 MR. HARKINS: Object to
6 form. Scope.
7 BY MR. STANOCH:
8 Q. You can put that aside.
9 MR. STANOCH: Why don't
10 you -- we take that five-minute
11 break you want.
12 MR. HARKINS: Okay. Is five
13 good with you or --
14 THE WITNESS: Yeah, five is
15 good with me.
16 THE VIDEOGRAPHER: The time
17 right now is 3:28 p.m. We are off
18 the record.
19 (Short break.)
20 THE VIDEOGRAPHER: The time
21 right now is 3:36 p.m. We're back
22 on the record.
23 BY MR. STANOCH:
24 Q. Sir, if you can flip to Page

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1 relationship, right?
2 A. Yeah. These were just
3 mentioned to you. There were others that
4 I don't have to mention.
5 Q. Well, I can only read the
6 ones that you do mention, right?
7 A. Right. But it's -- my
8 reference here "just to mention a few,"
9 is that of the inventory of SOPs that
10 pertain to these subjects, these are the
11 highlights. There are others. But these
12 are relevant highlights.
13 Q. Fair enough. And sitting
14 here today, can you tell me what other
15 ones there would be on this particular
16 point that you're opining on in Paragraph
17 103 besides the six that you identify?
18 A. Not from memory, no.
19 Q. That's fine. All right. So
20 I'm going to -- let's pull up the first
21 one here, CORP 0111.
22 MR. HARKINS: In the exhibit
23 box.
24 THE WITNESS: Oh.

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1 MR. STANOCH: Hold on.
2 Stand by. Okay. Exhibit 7.
3 (Document marked for
4 identification as Exhibit
5 Anderson-7.)
6 BY MR. STANOCH:
7 Q. This is the first example
8 SOP that you cite that Teva had in place
9 to manage the customer API supplier
10 relationship with ZHP and Mylan, right?
11 A. Yes.
12 Q. You'll see here on Page 1,
13 there's references.
14 Do you see that first
15 reference to CORP-176, quality technical
16 agreements?
17 A. Yes.
18 Q. You didn't review that
19 policy that's referenced, did you?
20 A. I may have considered it.
21 If it's not listed amongst those that I
22 have noted here, that was not one that I
23 mentioned in the listing.
24 But that's why I say "just

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1 to mention a few." There could be others
2 that would be one of those others.
3 Q. Well, I'll tell you -- I
4 mean, obviously we can agree CORP-176 is
5 not mentioned in Paragraph 103, right?
6 A. Correct.
7 Q. And I don't see any
8 reference to CORP-0176 in the exhibit
9 materials considered to your report
10 either, do you?
11 A. No, I don't believe that is
12 listed in here. If you say it's not
13 listed in here, I'm just going to go
14 ahead and consult this and see if this is
15 in fact the case.
16 I do not see that SOP listed
17 amongst these that I considered.
18 Q. Okay. So then it's fair to
19 say that CORP-1076 was not relied on or
20 considered by you, right?
21 A. Correct. 176 or 1076?
22 Q. 0176.
23
24

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[REDACTED]

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[REDACTED]

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[REDACTED]

14 (Document marked for
15 identification as Exhibit
16 Anderson-8.)
17 BY MR. STANOCH:
18 Q. Tell me when you're there.
19 A. Okay. I'm here.

[REDACTED]

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[REDACTED]

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[REDACTED]

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[REDACTED]

13 BY MR. STANOCH:
14 Q. Sir, I get to ask you what
15 documents you looked at, Mr. Anderson.
16 And my question is, did you do any
17 analysis of what's -- of your own to
18 confirm that the SOPs that you look at
19 and rely on in your report were final,
20 correct versions?
21 A. I asked for the final
22 versions and what was given to me was
23 represented as the final versions.
24 Q. Okay. So you did not do any

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1 analysis yourself to confirm that,
2 correct?
3 A. I asked for the current
4 version of the SOP and the -- and I was
5 supplied with what the current SOP was.
6 I don't know what you're
7 asking me to do apart from that. I don't
8 have insight into Teva's documents stash
9 or collection of SOPs apart from those
10 that were given to me.
11 I just don't understand how
12 you would expect me to research something
13 like this further, apart from my simple
14 asking for it.
15 Q. Right. And you don't know
16 one way or the other, until this exhibit,
17 in fact, whether there are potential
18 missing important issues or accidental
19 deletions from any of the SOPs that were
20 provided to you, correct?
21 A. This is the first time that
22 I've seen this e-mail, is an exchange
23 about two individuals wondering and
24 coming from one here, saying that he

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1 didn't -- he thought something pertaining
2 to auditing of third parties ought to be
3 in the latest revision of the SOP, and
4 was it something that was deleted from
5 the SOP.
6 We can go back to the
7 earlier version of the SOP and look at
8 that revision history and see if there's
9 any description of something having to do
10 with third-party sites that was deleted
11 from it.
12 Q. You haven't done that
13 undertaking as you sit here today, right?
14 A. I have not looked for that
15 specific topic, since you did not bring
16 this -- this topic was not brought to my
17 attention until you just brought it to me
18 now.
19 Q. Fair enough. Let's put that
20 one aside.
21 The next one that you cite
22 in this paragraph is CORP-0539, correct?
23 A. CORP-0539?
24 Q. CORP-0539, correct. That's

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1 the one.
2 A. That is the next one, yeah.
3 MR. STANOCH: Okay.
4 Exhibit 9.
5 (Document marked for
6 identification as Exhibit
7 Anderson-9.)
8 BY MR. STANOCH:
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
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18 [REDACTED]
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Page 336

1 there?

2 Q. Not yet. I'm happy to turn

3 to one, if you need to. But, you know, I

4 believe you look at FDA inspections of

5 Jerusalem from -- what is it, 2011 to

6 2018; is that right?

7 A. Let me confirm dates that

8 FDA inspections occurred.

9 I comment on those that

10 occurred during the time that valsartan

11 was being marketed, so that would not

12 include 2011, as far as the inspection

13 itself concerned.

14 Q. I can help you out. I think

15 it's starting on Page 42, you have a

16 heading, "Findings From Audits Conducted

17 At Teva Companies By FDA." Is that

18 helpful?

19 A. It is. Thank you.

20 Q. Great. And it looks like

21 you discuss two FDA inspections at the

22 Malta facility, one in 2014 and one in

23 2017, right?

24 A. Correct.

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[REDACTED]

16 Q. Okay. Put that aside.

17 MR. STANOCH: Stand by.

18 BY MR. STANOCH:

19 Q. In your report you have a

20 discussion about the FDA inspection of

21 Teva's Jerusalem and Malta facilities,

22 right?

23 A. I comment on that. Is there

24 a specific paragraph you're going to

Page 337

1 Q. And then you discuss two FDA

2 inspections of the Teva Jerusalem

3 facility, one in 2013 and one in 2015; is

4 that right?

5 A. That is correct.

6 Q. Are you aware that the FDA

7 inspected Teva's Jerusalem facility in

8 2019, sir?

9 A. They may have inspected in

10 2019; however, that was at a time that

11 was outside of the time that valsartan

12 was being manufactured and distributed.

13 So I did not make it a point to review to

14 any depth, to the point of commenting,

15 any inspections that occurred at Teva in

16 2019.

17 Q. Are you aware that the FDA's

18 inspection of Teva's Jerusalem facility

19 in 2019 focused on valsartan among other

20 things?

21 A. I don't recall that.

22 Q. Would that be pertinent to

23 your analysis of FDA inspections of

24 Teva's Jerusalem facility if the 2019

Page 338

1 inspection focused on the valsartan
2 issues prior to the recalls?
3 A. I -- prior to the recall
4 would mean that was in 2018 or before.
5 So an audit took place in 2019, while it
6 may have mentioned valsartan that was
7 manufactured prior to the recall, that is
8 informational, as far as my report is
9 concerned.
10 So I only focused on audits
11 which occurred during the time that Teva
12 was marketing valsartan products.
13 Q. It's not unusual in your
14 experience, is it, sir, for an FDA
15 inspection to look retrospectively at
16 things that have happened in the past?
17 A. That is common.
18 Q. Right. So it wouldn't
19 necessarily be surprising to you, if the
20 FDA, in 2019, just a few months after all
21 the recalls began, inspected Teva's
22 Jerusalem facility and focused on the
23 situation concerning the recalls of
24 valsartan the year earlier, correct?

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1 A. That would not be odd for
2 them to take into the history of what the
3 OSD facility made and when.
4 MR. STANOCH: I'll mark as
5 Exhibit 17.
6 (Document marked for
7 identification as Exhibit
8 Anderson-17.)
9 BY MR. STANOCH:
10 [REDACTED]
11 [REDACTED]
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18 Q. You're not offering any
19 opinion in your report whatsoever on the
20 outcome of the FDA's 2019 inspection of
21 Teva's Jerusalem facility, are you?
22 A. I am not offering an opinion
23 apart from what I'm reading here on the
24 e-mail trail that you supplied me.

<p>Page 350</p> <p>1 Q. In your report, you're not 2 offering any opinions whatsoever on the 3 FDA inspection of the Teva Jerusalem site 4 in 2019, correct? 5 A. No, I am not. 6 Q. And are you aware that the 7 Teva Jerusalem site that had made 8 valsartan was shut down? 9 A. I'm aware of that, yes. 10 Q. All right. Do you know 11 when? 12 A. I don't recall the exact 13 date. 14 Q. Do you know the precise -- 15 A. I had no reason to ask -- 16 Q. Do you know the precise 17 reasons why it was shut down? 18 MR. HARKINS: Object to 19 form. Foundation. Scope. 20 Speculation. 21 THE WITNESS: I don't know 22 everything that informed Teva with 23 respect to the decision to shut 24 down the OSD facility.</p> <p>Page 351</p> <p>1 BY MR. STANOCH: 2 Q. Right. You have no idea 3 what the reasons were for why Teva shut 4 down the Jerusalem facility, right? 5 A. I don't have knowledge of 6 specific reasons why that occurred. 7 Q. And then in terms of the 8 Malta facility, you are aware, are you 9 not, that Teva shifted production of 10 valsartan away from the Malta facility to 11 a different one? 12 A. I believe I recall seeing 13 that somewhere. 14 Q. Where did it shift the 15 production to? 16 A. I don't recall where that 17 was either. 18 Q. Why did Teva do that? 19 MR. HARKINS: Objection to 20 form. Foundation. Speculation. 21 THE WITNESS: I do not know. 22 BY MR. STANOCH: 23 Q. All right. So you have no 24 idea one way or the other of whether Teva</p>	<p>Page 352</p> <p>1 switched production away from the Malta 2 facility because of issues relating to 3 valsartan or not, correct? 4 MR. HARKINS: Object to 5 form. Foundation. Speculation. 6 Scope. 7 THE WITNESS: I don't know 8 why the valsartan product was 9 moved to another facility. 10 BY MR. STANOCH: 11 Q. Right. And similarly with 12 the Teva Jerusalem facility, you don't 13 know one way or the other about whether 14 the valsartan situation was a factor in 15 the closure of that facility, correct? 16 MR. HARKINS: Form. Same. 17 THE WITNESS: The closure of 18 these facilities, again, happened 19 after Teva ceased manufacturing 20 and marketing the drug product. 21 So I limited my commentary 22 as it pertained to inspections and 23 things having to do with those 24 inspections to times when</p> <p>Page 353</p> <p>1 valsartan was being marketed. 2 So the reasons why those 3 plants shut down was not something 4 that I deemed it necessary to take 5 into consideration. 6 BY MR. STANOCH: 7 Q. Are you aware of anything 8 that suggests that Teva was aware that 9 Mylan was using a third-party vendor, 10 Lantech, to manage the solvent recovery 11 process for the manufacture of valsartan 12 API? 13 A. Please rephrase that 14 question again. 15 Q. Sure. 16 MR. HARKINS: And, Dave, I 17 don't know if you're getting to a 18 new topic. We're about an hour 19 and a half on. So we'd like a 20 quick break whenever you find a 21 good time. 22 MR. STANOCH: If he wants a 23 quick break now, that's fine. 24</p>
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1 BY MR. STANOCH:
2 Q. Do you want a quick break,
3 Mr. Anderson?
4 A. Let's have a quick break.
5 MR. STANOCH: Okay.
6 THE VIDEOGRAPHER: The time
7 right now is 5:01 p.m. We are off
8 the record.
9 (Short break.)
10 THE VIDEOGRAPHER: The time
11 right now is 5:08 p.m. We're back
12 on the record.
13 BY MR. STANOCH:
14 Q. Welcome back, Mr. Anderson.
15 Did you talk to anybody besides your
16 counsel during the break?
17 A. Nobody else.
18 Q. Did you look at any
19 documents?
20 A. No, I did not.
21 Q. You didn't e-mail or text
22 anybody, did you?
23 A. No, I did not.
24 Q. Okay. And you're aware, are

Page 355

1 you not that Mylan was using a
2 third-party vendor, Lantech, to manage
3 the solvent recovery process for its
4 manufacture of valsartan API, correct?
5 A. I learned that that was the
6 case.
7 Q. You don't opine anywhere in
8 your report, do you, that Teva was aware
9 of that fact?
10 A. I do not opine in that
11 context, no.
12 Q. And is it correct that you
13 are not aware of any facts suggesting
14 that Teva was aware that Mylan was using
15 a third-party vendor, Lantech, to manage
16 the solvent recovery process for the
17 manufacture of valsartan API?
18 A. I don't recall any document
19 where Teva was found knowledgeable prior
20 to discontinuing the production of
21 valsartan.
22 Q. Do you agree that whether an
23 API supplier is using recovered solvents
24 is potentially pertinent from a cGMP

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1 quality standpoint?
2 A. Not necessarily.
3 Q. You disagree with that?
4 A. I said not necessarily.
5 Q. Well, Teva knew that ZHP
6 used recovered solvents in some of its
7 API processes, right?
8 A. I know that from
9 investigations that Teva undertook and
10 information that they learned from Mylan
11 at times after the marketing of valsartan
12 ceased.
13 Q. I want to make sure you
14 understood. I was talking about ZHP.
15 Were you aware that Teva
16 knew that ZHP used recovered solvents in
17 some of ZHP's API processes?
18 A. That is not something that
19 I'm aware of. I've not seen any
20 documents to suggest that Teva did know
21 this.
22 MR. STANOCH: Okay. Well,
23 why don't you pull up -- stand by.
24

Page 357

1 BY MR. STANOCH:
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■ [REDACTED]

9 BY MR. STANOCH:

10 Q. You agree --

11 A. It mentioned, as I recall,

12 that they even went out to other third

13 parties to have this done.

14 Q. You agree that Teva did not

15 know prior to summer of 2018 that Mylan

16 was using recovered solvents in the

17 manufacture of valsartan API being sold

18 to Teva, right?

19 MR. HARKINS: Form. Scope.

20 THE WITNESS: By ZHP? Or by

21 Mylan?

22 BY MR. STANOCH:

23 Q. No, sir.

24 Do you agree that Teva did

Page 363

1 not know prior to the summer of 2018 that

2 Mylan was using recovered solvents in the

3 manufacture of valsartan API being sold

4 to Teva?

5 MR. HARKINS: Objection to

6 form. Scope.

7 THE WITNESS: I'm recalling

8 one of the audits reports that I

9 just described where there was

10 blending of same solvents with

11 other lots of solvents that were

12 on hand.

13 I don't recall directly from

14 memory whether that involved

15 recovered solvents or just simply

16 solvents that were on hand.

17 But in any case, they were

18 qualified for further use in

19 production at Mylan. That is what

20 I believe I recall.

21 BY MR. STANOCH:

22 Q. What Teva audit report of

23 Mylan do you believe makes any mention of

24 the use of recovered solvents in the

Page 364

1 manufacture of valsartan API?

2 A. I don't recall which audit

3 report that was. There were a couple

4 audit reports. I do not recall which one

5 that was.

6 Q. And you're not sure one way

7 or the other whether they mentioned

8 recovered solvents specifically, correct?

9 A. I'm not recalling

10 immediately, no. I do know they -- I

11 have a reasonable belief that I recall

12 that they blended same solvents together,

13 new and those that were on hand, in order

14 to have enough solvent to be able to

15 proceed to production.

16 Q. And you're implying there

17 that you think it might have been a fresh

18 barrel -- an unopened barrel of solvent

19 and maybe one that had already been half

20 used to get the full amount that they

21 needed; you're not suggesting that it was

22 saying some of that was recovered or

23 recycled, are you?

24 A. What I'm saying is I don't

Page 365

1 recall it. I'm recalling that there was

2 a blending and a certification.

3 I'm not recalling if it said

4 specifically that it was recovered

5 solvents that would be blended with new

6 solvents. I am reasonably certain that

7 it was solvents which were on hand.

8 Q. You are not opining anywhere

9 in your report, are you, that Teva knew

10 that Mylan was using recovered solvents

11 in the manufacture of valsartan API, are

12 you?

13 A. I have commented on what

14 John Quick said as it pertains to

15 recovered solvents.

16 Again, if this was something

17 that showed up in the inspection report

18 for Mylan, and it was mentioned that

19 recovered solvents were those that were

20 blended -- but I don't happen to have an

21 immediate recollection of that -- Teva

22 then would have known at that time that

23 Mylan was using recovered solvents as

24 well as fresh solvents.

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1 Q. I'm asking about your
2 report, sir. Okay. Are you with me,
3 Mr. Anderson?
4 A. Yeah.
5 Q. In your report, where do you
6 opine that Teva knew that Mylan was using
7 recovered solvents in the manufacture of
8 valsartan API?
9 A. I'm not recalling that
10 citation at this moment.
11 But I've described to you
12 what I'm recalling from the audit reports
13 themselves.
14 Q. Did you look at any of the
15 FDA inspection reports of Lantech, the
16 third party vendor that Mylan was using
17 to manage the solvent recovery process?
18 A. No, I did not.
19 Q. Don't you think it would be
20 important from a cGMP standpoint to
21 understand what the FDA said about the
22 vendor that was managing the solvents
23 that were found to be the potential root
24 cause of the NDEA contamination in

Page 367

1 Mylan's valsartan API?
2 MR. HARKINS: Form. Vague.
3 THE WITNESS: What FDA had
4 to say about that processing
5 facility was something that was
6 related at a time after valsartan
7 was being manufactured and
8 distributed by Teva with API that
9 was sourced from Mylan.
10 So there was an inspection
11 that did take place afterward, and
12 FDA had comments about that.
13 BY MR. STANOCH:
14 Q. If Teva did not know --
15 strike that.
16 As Teva did not know that
17 Mylan was using Lantech to manage the
18 recovered solvents process, Teva would
19 not even know to ask questions about
20 Lantech's cGMP compliance, correct?
21 A. If Teva didn't know that
22 Lantech specifically was being used as a
23 vendor, Teva would not have reason to ask
24 questions about Lantech.

Page 368

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Page 373

[REDACTED]

12 BY MR. STANOCH:

13 Q. Mm-hmm. And you make it a

14 point in Paragraph 142 of your report to

15 suggest that Teva had no vendor agreement

16 with Lantech, so it was in no position to

17 require Lantech to let it audit or manage

18 the solvent recovery process, right?

19 A. That's correct. Teva was

20 not Lantech's direct customer. So there

21 were not supplier agreements because they

22 were not a direct supplier to Teva. They

23 were a supplier of a service to Mylan.

24 And it would have been an

<p>Page 374</p> <p>1 agreement with Mylan that would have been 2 operative for managing the quality 3 aspects of the recovered solvents that 4 Mylan was subsequently then used to 5 manufacture API. 6 Q. Mylan, though, was a direct 7 customer of Teva, correct? 8 A. That's correct. 9 Q. And Teva had the authority, 10 did it not, to require Mylan to ensure 11 that any of Mylan's own subcontracted 12 vendors were taking adequate cGMP quality 13 assurance steps, correct? 14 MR. HARKINS: Object to 15 form. Vague. 16 THE WITNESS: That is not 17 something that is in every single 18 agreement that I've ever seen. It 19 is just that suppliers, as I've 20 seen such contracts making 21 reference to other parties here, 22 just that it would be the 23 responsibility of that primary 24 vendor, in this case, Mylan, to</p>	<p>Page 376</p> <p>1 as to the reason why NDEA arose and was 2 evident in Mylan's API. 3 So whether they had a 4 quality agreement or not in place, that 5 did not prohibit what was necessary 6 dialogue that had to transpire between 7 Teva and Mylan on topics having to do 8 with cGMP compliance and conforming to 9 specifications that were agreed to with 10 Mylan contractually as a supplier of API 11 to Teva and the ability of Teva to be 12 able to perform quality audits on a 13 schedule negotiated with Teva -- 14 negotiated with Mylan. 15 Q. You don't cite anywhere in 16 your report any dialogue between Teva and 17 Mylan about the cGMP compliance issues 18 with respect to the recovered solvent 19 process for the manufacture of valsartan 20 API, do you? 21 A. I do not speak to any 22 dialogue that Mylan had with Lantech 23 about which they informed Teva, no. I 24 don't speak of that.</p>
<p>Page 375</p> <p>1 support drug substance that 2 conforms to cGMP, and that it 3 managed its own quality system. 4 And by extension, that would 5 mean managing its relationship 6 with those who furnish services to 7 them to support their quality 8 system, in this case, Lantech. 9 BY MR. STANOCH: 10 Q. Well, in here, we don't have 11 any agreement between Teva and Mylan, 12 right? 13 A. We do not have a quality 14 agreement. No, we do not. But -- 15 Q. In fact -- go ahead. 16 A. But that -- as of the 17 revelation of NDEA by Mylan, ultimately 18 by way of Swissmedic information and the 19 identification of Mylan as supplier of 20 API, it did not prevent Teva from 21 maintaining a relationship that involved 22 necessary dialogue as it pertained to the 23 control of NDEA in Mylan's API, and/or 24 getting to the investigation conclusion</p>	<p>Page 377</p> <p>1 Q. And you don't cite anywhere 2 any dialogue between Teva and Mylan about 3 the recovered solvent process at all, do 4 you? 5 A. Again, only what I recalled 6 from what was cited in the report as a 7 matter-of-fact point that older solvents 8 are blended with newer solvents, and that 9 may, although I don't recall it 10 immediately, that may have also included 11 recovered solvents. 12 Q. You're not sure sitting 13 here -- 14 A. The source of recovered -- 15 Q. I'm sorry. Go ahead. 16 A. Yeah, the source of the 17 recovered solvents were not something 18 that was at issue. 19 Q. Okay. So why you say there 20 was not preventing Teva and Mylan having 21 a dialogue in the absence of a quality 22 agreement, you don't cite any evidence 23 that there was any such dialogue with 24 respect to the recovered solvent process</p>

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1 for valsartan API manufacturing, do you?
2 MR. HARKINS: Objection to
3 form. Vague.
4 THE WITNESS: There was
5 dialogue that transpired after
6 Teva ceased marketing valsartan.
7 I do know that they were in
8 contact with and in dialogue with
9 Mylan certainly at that time.
10 I don't know what the level
11 of dialogue was that Teva had with
12 Mylan on the subject of NDEA prior
13 to December of 2018.
14 BY MR. STANOCH:
15 Q. Do you cite in your report,
16 sir, any evidence of any dialogue between
17 Teva and Mylan prior to the summer of
18 2018 about the use of recovered solvents
19 in the manufacture of valsartan API?
20 MR. HARKINS: Same
21 objection.
22 THE WITNESS: Again, as I
23 pointed out what my recollection
24 of the audit report -- one of the

Page 379

1 audit reports at least, if not
2 both, mentioning the blending of
3 solvents on hand with new solvents
4 that were coming in and having
5 them qualified for suitability for
6 use in further production.
7 I do not recall immediately
8 whether they mentioned recovered
9 solvents in that description, but
10 I do recall a blending of solvents
11 in this way.
12 So is that dialogue? I
13 would say that's dialogue.
14 BY MR. STANOCH:
15 Q. Well, you don't know whether
16 it was recovered solvents or not, do you?
17 A. I am telling you that I
18 don't recall exactly whether it said it
19 was recovered solvents or not. I would
20 have to review the -- review the reports
21 there.
22 I don't recall that there
23 was a deficiency that Teva lodged with
24 Mylan about the fact that they were using

Page 380

1 recovered solvents, because as a
2 practice, utilization of recovered
3 solvents in production is not a -- is
4 commonly not an issue in drug substance
5 manufacturing.
6 Q. Well, if Teva didn't know,
7 then they wouldn't be able to lodge an
8 objection or observation about it, could
9 they?
10 A. What I'm saying, again, is,
11 it is possible that they did know. And
12 the reference that I'm making that,
13 again, I am trying to recall from memory
14 if it included recovered solvents or just
15 old solvents.
16 But they were confident that
17 those solvents -- Teva was confident that
18 those solvents were suitable for use
19 because they met specifications for their
20 continued use in production with metrics
21 that Mylan had set up, governed by its
22 quality system to be able to proceed in
23 manufacturing with solvents that were
24 combined in this fashion.

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1 Q. Are you saying that Teva
2 might have known and said it was okay to
3 keep using recycled solvents in Mylan's
4 manufacture of valsartan API?
5 MR. HARKINS: Objection to
6 form. Misstates testimony.
7 THE WITNESS: What I'm
8 saying is there was possibly a
9 reference of recovered solvent
10 every bit as much as there was a
11 mention of recovered solvent in
12 the ZHP audit report.
13 This was -- the use of
14 recovered solvents was not a --
15 something that raised a concern by
16 Teva of ZHP. And the fact that
17 ZHP recovered solvent was not, to
18 my recollection, one of the
19 reasons why NDMA was found in
20 ZHP's API.
21 We're talking about NDEA in
22 the context of -- in the context
23 of Mylan and that it was
24 attributable, upon further

Page 382

1 evaluation, to something having to
2 do with recovered solvents in the
3 way that they were recovered at
4 Lantech and subsequently utilized
5 in purification processes at
6 Mylan.
7 BY MR. STANOCH:
8 Q. Tell me as specifically as
9 possible where you think this reference
10 to recycled solvents in the manufacture
11 of valsartan API at Mylan appears in Teva
12 audit reports?
13 A. I don't recall which of the
14 audit reports I thought it was in. But I
15 believe that I recall this residing in
16 one of those reports having to do with
17 older solvents, whether they were
18 recovered or just solvents on hand
19 blended with newer lots of solvents, and
20 then tested and qualified according to
21 specifications set for them at that time
22 for further use in API production.
23 Q. Right. You don't know if
24 that reference that you think you might

Page 383

1 recall, and can't tell me where it is,
2 whether it was just older solvents being
3 blended or recycled and new solvents
4 being blended, right?
5 A. Right. I don't recall
6 exactly.
7 Q. That's fine. That's fair.
8 Sir, in your appendix you
9 have a number of charts that you have
10 regarding observations from government or
11 Teva audits and responses and whether the
12 observations or responses suggest
13 presence of NDMA or NDEA; is that right?
14 A. That none of the responses
15 indicated that NDMA or NDEA were present
16 or even suggested it.
17 Q. And you can pull that up. I
18 think it's an attachment to your report,
19 which you should have in front of you,
20 right?
21 A. Yes, I do. I'm starting
22 here on the very first page of the
23 appendix.
24 Q. And your column on the

Page 384

1 right, "Observation or response suggest
2 presence of NDMA or NDEA," there you're
3 saying whether the observation was
4 evidence that NDMA or NDEA was present?
5 MR. HARKINS: Object to
6 form.
7 THE WITNESS: That my --
8 that the observation or response
9 suggests that presence of NDMA or
10 NDEA might be present, that is yes
11 or no, and what is the reason for
12 my saying so.
13 BY MR. STANOCH:
14 Q. The actual presence of an
15 impurity is just one potential basis for
16 a drug being adulterated, correct?
17 A. Presence of an impurity
18 beyond a controlled limit specified for
19 it.
20 Q. And we talked about this
21 much earlier today. You agreed that a
22 drug could still be adulterated even in
23 the absence of an impurity if it was not
24 manufactured in conformance with current

Page 385

1 good manufacturing practices, correct?
2 A. That's correct.
3 Q. So just because an
4 observation from a given inspection or
5 finding does not suggest the actual
6 presence of NDMA or NDEA does not mean
7 there was not a potential deviation from
8 cGMP, correct?
9 A. Correct.
10 Q. And in your appendix, you
11 address, among other things, the FDA
12 for-cause inspection of ZHP in 2018,
13 correct?
14 A. I do.
15 Q. And this was the FDA's
16 inspection of ZHP following the news
17 about NDMA in the summer of 2018, right?
18 A. It occurred from July 23rd
19 to August 3rd, 2018. So this for-cause
20 inspection followed on the revelation
21 that NDMA was present.
22 Q. Right, this was after ZHP
23 disclosed to Teva and others about NDMA
24 in June 2018, right?

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1 A. Correct.

2 Q. And in fact, the very reason

3 for this for-cause inspection was the

4 NDMA contamination of valsartan, right?

5 A. I believe that was one of

6 the topics here. I don't recall

7 necessarily that it was the only topic

8 that was the subject of the for-cause

9 inspection, if I review this just a

10 second to gain some insight on whether

11 there were other products possibly that

12 were reviewed in the for-cause

13 inspection. That's possible.

14 But, that you're focusing on

15 valsartan with respect to this for-cause

16 inspection, is accurate.

17 Q. And you can look through

18 your chart, but I think in your

19 right-most column you say no, that every

20 observation in response did not suggest

21 the presence of NDMA or NDEA, right?

22 A. Correct.

23 Q. Wasn't the FDA for-cause

24 inspection of ZHP the basis for the FDA's

Page 387

1 warning letter to ZHP a few months later?

2 A. It formed certainly some of

3 the basis. Whether it informed all of

4 it, I cannot say.

5 Q. You know that FDA issued a

6 warning letter to ZHP in -- was it late

7 2018, right?

8 A. I believe that was

9 November 29, 2018, yeah.

10 Q. I agree. I appreciate the

11 specificity.

12 And among other things in

13 that letter, the FDA determined that

14 ZHP's valsartan API was adulterated,

15 right?

16 A. As of that date they

17 declared that valsartan manufactured by

18 ZHP, valsartan products are adulterated.

19 Q. And it was adulterated in

20 part because of the issues concerning

21 lack of cGMP compliance with respect to

22 the manufacture of valsartan API, right?

23 A. There were detailed

24 citations in the warning letter that

Page 388

1 formed the basis for that, which included

2 observations as well as testing that FDA

3 had performed on certain valsartan lots.

4 Q. And the observations you

5 reference are the observations made a few

6 months prior during the for-cause FDA

7 inspection in July through August of

8 2018, right?

9 A. Correct.

10 Q. So how could you say that

11 the FDA's inspection of ZHP in the summer

12 of 2018 did not suggest the presence of

13 NDMA and NDEA when just a few months

14 later, the FDA issues a warning letter

15 saying that your product is adulterated

16 because your process is going to result

17 in NDMA?

18 A. What FDA did, as I just

19 mentioned, was take those samples from

20 ZHP and performed analyses of their own.

21 And on the basis of that evidence, it was

22 confirmed that there was presence of NDMA

23 in ZHP's API.

24 So observations were made

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1 prior to samples being taken and FDA

2 performing their own independent testing

3 thereof.

4 So the warning letter is

5 informed by observations made and on the

6 basis of testing that FDA had performed

7 themselves.

8 Q. So unless an observation

9 was, "We found NDMA in your valsartan API

10 during this inspection," then you would

11 say no, the observation does not suggest

12 the presence of NDMA?

13 MR. HARKINS: Objection to

14 form. Misstates the testimony.

15 Misstates the report.

16 THE WITNESS: There's

17 nothing in the observations that

18 FDA made that suggest or even

19 point to or implicate the presence

20 of NDMA in -- or NDEA in valsartan

21 API at the time of the inspection.

22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

Page 390

[REDACTED]

Page 392

[REDACTED]

Page 391

[REDACTED]

Page 393

[REDACTED]

24

Page 394

1 BY MR. STANOCH:
2 Q. Okay. You're not aware of
3 anything that prevented Teva from making
4 its own observation about this inadequate
5 investigation of unknown peaks, say,
6 during the May 2018 Teva audit of ZHP?
7 MR. HARKINS: Form.
8 Speculation.
9 THE WITNESS: Could you
10 rephrase your question, please?
11 BY MR. STANOCH:
12 Q. Sure.
13 You don't opine on anything
14 that prevented Teva from making the same
15 observation about ZHP's inadequate
16 investigation of unknown peaks for the
17 valsartan intermediates that the FDA
18 identifies during Teva's May 2018 audit
19 of ZHP?
20 MR. HARKINS: Same
21 objection.
22 THE WITNESS: We can go back
23 to the 2018 audit and if there is
24 an observation that Teva made in

Page 395

1 May of 2018, that matches this
2 observation that was made by FDA,
3 I would invite you to find it.
4 BY MR. STANOCH:
5 Q. Well, I'm going to invite
6 you, Mr. Anderson, to tell me, did Teva
7 ever review the deviation that the FDA
8 observed in their 2018 investigation
9 itself?
10 A. They may have. But again,
11 this was at a time, in August of 2018,
12 when Teva had ceased to market valsartan.
13 It is possible that the
14 deviation investigation was something
15 that Teva elected to explore on its own
16 to learn more about the nature of the
17 quality of the deviation investigation
18 themselves and develop an opinion about
19 it.
20 But at the time that that
21 was occurring, Teva was not marketing
22 valsartan that was manufactured by ZHP.
23 Q. I'm looking at your appendix
24 about this observation, and the deviation

Page 396

1 was initiated, according to you,
2 October 10, 2017. So that -- that was
3 well prior to Teva's recalls of
4 valsartan, correct?
5 A. The investigation at ZHP was
6 something that was undertaken earlier, by
7 your account.
8 Q. And Teva, to your knowledge,
9 never evaluated ZHP's October 10, 2017
10 investigation into the deviation, which
11 ultimately led to -- in part, to the FDA
12 warning letter of ZHP?
13 A. I don't know what kind of
14 dialogue transpired as it pertained to
15 that deviation.
16 Q. Did you even attempt to map
17 whether, during its audits Teva had the
18 opportunity to look at the same things
19 that the FDA looked at at ZHP in 2018?
20 MR. HARKINS: Form. Vague.
21 THE WITNESS: Are you saying
22 following on any audit that FDA
23 had of ZHP? I'm not understanding
24 your question here.

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1 BY MR. STANOCH:
2 Q. Sure.
3 The FDA inspection in 2018
4 noted, among other things, a deviation at
5 ZHP dated October 10, 2017, right?
6 A. Okay.
7 Q. And that was one of the
8 things that they cite in the warning
9 letter about failing to do testing and
10 adequate investigation that led to the
11 warning letter, right?
12 A. Respectfully, could you
13 point me to the exact observation? These
14 are numbered in my -- excuse me -- in
15 my -- excuse me. I need water.
16 Q. 3D.
17 A. Let me get there. Okay
18 Observation 3D, did I hear you correctly?
19 Q. Yes, sir.
20 A. Okay. I am at that
21 observation. Your question, please?
22 Q. You see it was initiated
23 October 10, 2017, by ZHP?
24 A. I do.

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1 Q. You're not aware of any --
2 you're not aware of whether Teva was
3 aware of that deviation at any time prior
4 to the summer of 2018, are you?
5 A. I see that I was also
6 correct that this involved an
7 intermediate valsartan product, the
8 intermediate condensate HCl specifically.
9 A deviation with respect to
10 an intermediate that was being
11 investigated at the time is not something
12 that I necessarily would have expected
13 them to share with -- with Teva. It's
14 possible that this deviation pertained to
15 a lot of valsartan that was not sold to
16 Teva. It could have been sold to another
17 customer.
18 But it does happen to have
19 this amount of detail in it as FDA has
20 cited it.
21 Q. Mr. Anderson, I'm going to
22 ask you to listen to my question. Are
23 you aware of whether Teva knew of this
24 deviation at any time prior to the summer

Page 399

1 of 2018?
2 A. I do not know.
3 Q. Are you aware of anything
4 that prevented Teva from asking ZHP about
5 this deviation prior to the summer of
6 2018?
7 MR. HARKINS: Form. Vague.
8 THE WITNESS: I do not know
9 that Teva had a reason to know
10 about this particular deviation,
11 as it may not have applied to API
12 that they had purchased from ZHP.
13 BY MR. STANOCH:
14 Q. So then you're not aware of
15 anything that prevented Teva from asking
16 ZHP about this deviation prior to the
17 summer of 2018?
18 A. Having knowledge of this
19 deviation is something that would not be
20 expected routinely for a substance that
21 was not incorporated into a Teva product.
22 So there is no reason to expect that ZHP
23 would have to inform Teva regarding an
24 intermediate deviation that was

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1 accomplished on behalf of -- or in the
2 course of manufacturing API on behalf of
3 another customer.
4 I don't know the detail
5 here. But there is no reason why Teva
6 would necessarily have to be informed of
7 every single deviation that pertains to
8 valsartan manufacture, and particularly
9 those deviations that had nothing to do
10 with API that they had specifically
11 purchased.
12 Q. You don't know one way or
13 the other whether Teva knew about this
14 deviation prior December of 2018,
15 correct?
16 A. I do not know.
17 Q. Did you review any Teva SOP
18 concerning whether a process change
19 should be classified as PAS or CBE?
20 A. I did not review any SOP
21 that Teva had as it pertained to that
22 kind of classification. That type of
23 classification is something that is
24 ultimately decided upon by FDA in their

Page 401

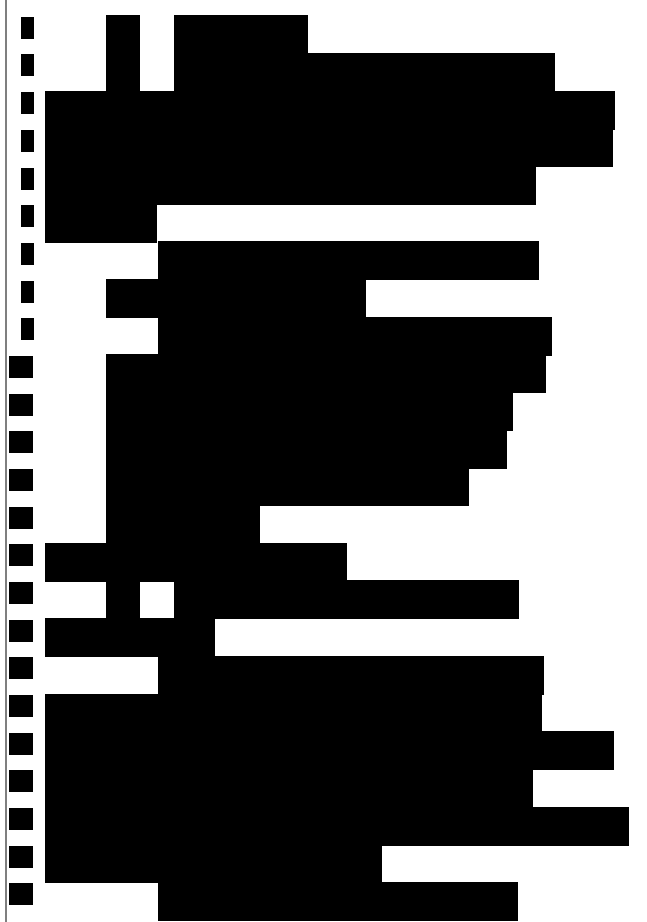
1 opinion, regardless of what the
2 submission that is made by the applicant.
3 For instance, an applicant
4 may submit a Changes Being Effectuated 30,
5 supplemental submission to their ANDA,
6 and describe what the change is in there.
7 And according to their opinion, it is
8 their belief that a CBE-30 filing is
9 appropriate.
10 But FDA may elevate the
11 level of that submission because, in
12 their opinion, they believe the matters
13 that are covered in that submission rise
14 to the level of requiring a preapproval
15 designation for that submission, not
16 merely a CBE-30.
17 Q. Did you review any Actavis
18 policies, procedures, or practices as to
19 whether the company should classify a
20 process change as PAS or CBE?
21 A. I don't recall that I did.
22 MR. STANOCH: Let's go off
23 the record.
24 THE VIDEOGRAPHER: The time

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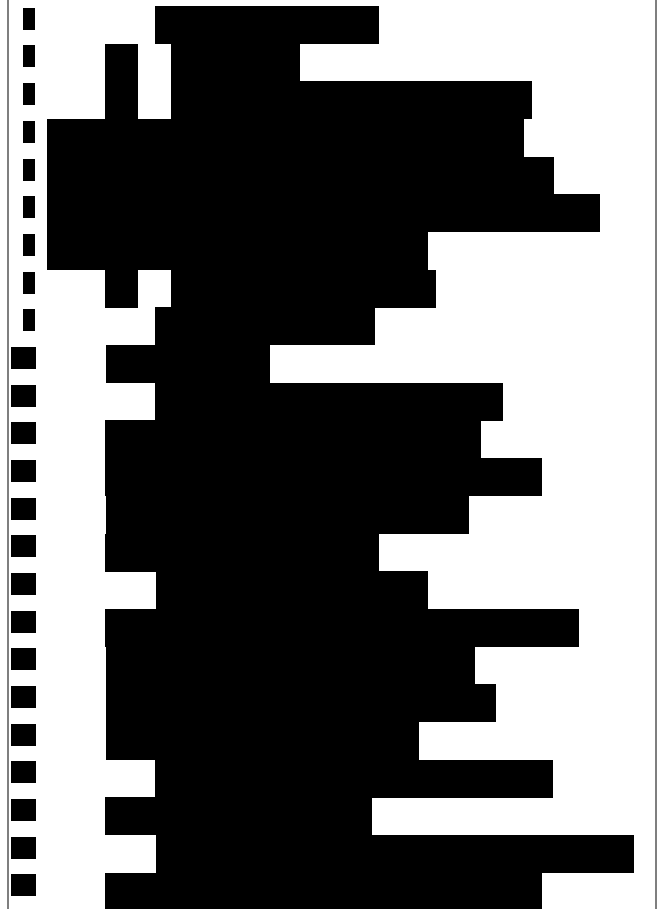
1 right now is 6:00 p.m. We are off
2 the record.
3 (Short break.)
4 THE VIDEOGRAPHER: The time
5 right now is 6:38 p.m. We are
6 off -- we're back on the record.
7 BY MR. STANOCH:
8 Q. Just a few more questions,
9 Mr. Anderson. I want to pull up again
10 the Narendra Vadsola transcript we looked
11 at earlier.
12 Do you recall that
13 transcript?
14 A. I do.



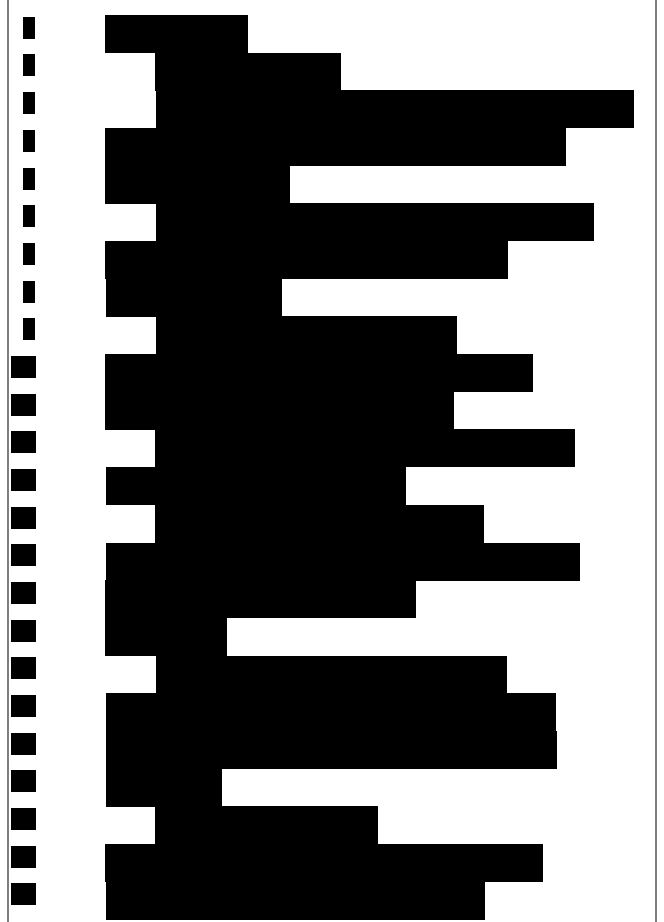
Page 403



Page 404



Page 405



Page 406

[REDACTED]

Page 408

[REDACTED]

23 Q. All right. Put that aside.
24 Sir, did you write your own

Page 407

[REDACTED]

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1 report here in this case?
2 A. I did.
3 Q. Did you prepare the appendix
4 to your report with the observation
5 chart?
6 A. I did.
7 Q. Did you prepare the
8 materials considered list appended to
9 your report?
10 A. I did.
11 Q. Did you ever do any
12 consulting work for any of the defendants
13 in this litigation prior to this case?
14 A. No, I have not.
15 Q. Actually, earlier you said
16 you don't know who the defendants are, so
17 I guess you're not sure. Is that fair?
18 A. I'll say I read Mr. Quick's
19 report, and to the degree that I was
20 familiar on having read any of those
21 names there, no, I have not consulted for
22 any of those. So I'll leave it at that.
23 Q. Fair enough.
24 MR. STANOCH: I'm going to

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1 mark Exhibit 45 -- I'm sorry,
2 Exhibit 20.
3 (Document marked for
4 identification as Exhibit
5 Anderson-20.)
6 BY MR. STANOCH:
7 Q. This is a collection of the
8 invoices that we've been provided for
9 your work in this case. Can you see
10 those?
11 A. I'm refreshing. One moment,
12 please.
13 Q. I can try to screen share if
14 that's faster.
15 How's that? Can you see my
16 screen, sir?
17 A. I do see your screen.
18 Q. And you see there is an
19 invoice dated December 31, 2021; an
20 invoice dated January 31, 2022; and a
21 final invoice dated February 28th, 2022.
22 Is it correct that these are
23 all the invoices that have been issued
24 for your work in this case thus far?

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1 A. As of this time, correct.
2 Q. All right. And ProPharma,
3 that's just a consulting outfit through
4 which you were connected with Teva in
5 this litigation?
6 A. Yes. Actually, my services
7 are being made by way of a subsidiary of
8 ProPharma Group known as NDA Partners.
9 Q. Got it. And then it looks
10 like the amounts invoiced thus far, we
11 see about \$69,000 for your first invoice,
12 \$78,000 for your second invoice, and
13 \$30,000 and change for your most recent
14 February 2022 invoice, correct?
15 A. Correct.
16 Q. It looks like the total
17 is -- you've invoiced approximately
18 \$177,000 for your work to date?
19 A. If you add these numbers up
20 and they come to that amount and it is
21 accurate, I agree with it. I've not
22 added it up that way myself.
23 MR. STANOCH: I have no
24 further questions at this time for

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1 you, Mr. Anderson.
2 Thank you.
3 THE WITNESS: Thank you.
4 - - -
5 EXAMINATION
6 - - -
7 BY MR. HARKINS:
8 Q. All right. Tim, I will have
9 some questions for you. I figure we
10 should go ahead until the technology
11 gives out on us, which hopefully it
12 won't.
13 Are you good to go right
14 into it?
15 A. Yes.
16 Q. Okay. Good. All right.
17 MR. HARKINS: Dave, correct
18 me if I'm wrong. I don't believe
19 his CV has been introduced,
20 correct?
21 MR. STANOCH: Correct,
22 unless it was part of the report.
23 MR. HARKINS: I don't think
24 the version that you introduced

Page 413

1 had it as an attached exhibit. I
2 just want to confirm so we're not
3 introducing extra stuff.
4 BY MR. HARKINS:
5 Q. All right. Tim, if you go
6 to the DropBox and pull up what should be
7 introduced electronically as Exhibit 21.
8 MR. STANOCH: Sorry,
9 Mr. Harkins, it's also Exhibit A
10 to Exhibit 1, his report.
11 But any way you want to
12 proceed, I'm fine.
13 MR. HARKINS: Sure.
14 Can you pull up Exhibit 21?
15 Just to make sure it's dropped in
16 there correctly.
17 THE WITNESS: It's here,
18 correct.
19 (Document marked for
20 identification as Exhibit
21 Anderson-21.)
22 BY MR. HARKINS:
23 Q. Right. And Tim, if you go
24 down to review it quickly, is this an

<p>Page 414</p> <p>1 updated CV that you have prepared for us?</p> <p>2 A. It is.</p> <p>3 Q. And how can you tell it's</p> <p>4 the updated CV?</p> <p>5 A. Because I see revisions to</p> <p>6 this version of the CV that I made very</p> <p>7 recently and furnished to NDA Partners,</p> <p>8 who subsequently furnished a copy to you</p> <p>9 as an update.</p> <p>10 Q. And just to clarify, what</p> <p>11 are the revisions to your CV from the one</p> <p>12 that was submitted as an attachment to</p> <p>13 your report?</p> <p>14 A. The revisions include a</p> <p>15 heading that at one time on Page 5, read</p> <p>16 "Depositions," which was not entirely</p> <p>17 correct. And I changed the word to say</p> <p>18 "Legal," which in fact is correct.</p> <p>19 The reason it had to be</p> <p>20 corrected is because all of the case work</p> <p>21 that I list here did not necessarily</p> <p>22 include a deposition.</p> <p>23 However, for the assistance</p> <p>24 of anyone who is referring to this here,</p> <p>Page 415</p> <p>1 one can learn what it is in fact that I</p> <p>2 did do with respect to this case work;</p> <p>3 that is, whether I wrote a report only or</p> <p>4 I wrote a report and had a deposition or</p> <p>5 I had written the report, had a</p> <p>6 deposition, had court testimony, or</p> <p>7 possibly testimony as arbitration, or</p> <p>8 whether I just simply provided</p> <p>9 consultative work.</p> <p>10 So each one of these cases,</p> <p>11 in addition to having the dates on</p> <p>12 which -- or the years in the -- and</p> <p>13 states in which the cases were done and</p> <p>14 what type of service I provided to them</p> <p>15 is now much more clear.</p> <p>16 Q. Okay. Just to clarify, did</p> <p>17 you add any new matters to that section</p> <p>18 that you revised?</p> <p>19 A. No, I did not.</p> <p>20 Q. Other than changing the</p> <p>21 heading and clarifying some of the</p> <p>22 descriptions, did you make any other</p> <p>23 changes to that section?</p> <p>24 A. No other changes.</p>	<p>Page 416</p> <p>1 Q. Did you make any other</p> <p>2 changes to any other part of the CV?</p> <p>3 A. No, I did not.</p> <p>4 Q. Okay. And just for the</p> <p>5 benefit of the jury, just generally and</p> <p>6 briefly, give us a little description of</p> <p>7 your background, please.</p> <p>8 A. I celebrate my 40th career</p> <p>9 year this year. And I began right out of</p> <p>10 school with a technical temporary</p> <p>11 employment firm by the name of Clinton</p> <p>12 Research Consultants where I did three</p> <p>13 different assignments in a variety of</p> <p>14 technical veins, none of which were</p> <p>15 pharmaceutical.</p> <p>16 In 1984, I had my first job</p> <p>17 in the pharmaceutical industry in -- as</p> <p>18 an experimental formulations chemist,</p> <p>19 developing and validating methods, having</p> <p>20 to do with bioanalytical methods</p> <p>21 predominately for new formulations that</p> <p>22 were being developed at the Purdue</p> <p>23 Frederick research center.</p> <p>24 I went on for -- after that,</p> <p>Page 417</p> <p>1 after three years being there, I went on</p> <p>2 for another job which I took at Bayer</p> <p>3 Pharmaceuticals where I was in quality</p> <p>4 control and quality assurance for a total</p> <p>5 of five years.</p> <p>6 I joined the FDA after</p> <p>7 leaving Bayer and stayed with FDA's</p> <p>8 Office of Generic Drugs, where I served</p> <p>9 as a review chemist and was there for</p> <p>10 slightly more than two years.</p> <p>11 But then went back into</p> <p>12 industry and was hired by Sandoz</p> <p>13 Pharmaceuticals Corporation, where I was</p> <p>14 hired to build brand protection</p> <p>15 strategies for what were Sandoz flagship</p> <p>16 products at the time.</p> <p>17 These were clozapine,</p> <p>18 cyclosporine, bromocriptine,</p> <p>19 predominately at that time. And</p> <p>20 strategies that we were developing were</p> <p>21 related predominately to not only</p> <p>22 excellence in filing, but also in terms</p> <p>23 of bioequivalence development as well.</p> <p>24 The whole intention being</p>
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<p>Page 418</p> <p>1 that we would have the files ultimately 2 by which the generic industry would be 3 measured according to quality and 4 requirements for their submissions. 5 I left Novartis -- or 6 actually Sandoz, which when they merged 7 with Ciba Geigy, it became Novartis. I 8 left Novartis in February of 1996. 9 And 26 years ago, in 10 February, I formed my own consulting firm 11 which is specialized predominately in 12 chemistry and manufacturing controls 13 issues. 14 Q. And specifically, in what 15 context in your professional experience 16 have you worked with cGMPs and conducted 17 cGMP inspections? 18 A. I've conducted many cGMP 19 inspections in the context of mock 20 preapproval inspections, in terms of 21 preparing sites that were anticipating 22 FDA's visits and preparing them for that, 23 and in one particular instance, 24 accompanying that -- the clients at the</p> <p>Page 419</p> <p>1 time that the FDA was present to do their 2 inspection. 3 Also happened to be present 4 on another occasion where FDA just 5 happened to show up while I was doing my 6 inspection. 7 But those, in addition to 8 also performing such cGMP evaluations on 9 behalf of firms which are engaged in 10 merger and acquisition efforts to 11 evaluate certain aspects that have a cGMP 12 compliance component to them for purposes 13 of informing their investment decisions. 14 Q. And during your time prior 15 to your consulting work, did you also 16 work on issues related to cGMPs? 17 A. I did. 18 Q. Please explain. 19 A. Specifically, when I was at 20 Bayer. For instance, this was my first 21 introduction to the meaningful 22 significance of cGMP compliance in the 23 marketed product world. 24 As I said, I was there for</p>	<p>Page 420</p> <p>1 five years and was performing analytical 2 assays and overseeing the work of others 3 who were also performing analytical 4 assays for what were approved and in some 5 cases products which were also in 6 development. 7 Q. In addition to your work 8 with cGMPs and cGMP inspections, have you 9 reviewed any FDA cGMP inspections? 10 A. I have reviewed FDA cGMP 11 inspections in the form of FDA Form 483s 12 that have been issued. 13 Q. What's an initial 14 observation? 15 A. An initial observation is, 16 as the name suggests, a first 17 observation, a first statement that is 18 communicated that -- in the context of an 19 FDA inspection, it is the very first 20 observation that is made. 21 Typically on a 483 FDA, 22 arranges their observations in a manner, 23 in a descending sequence of priority. 24 Q. In your experience, how</p> <p>Page 421</p> <p>1 common is it for an initial observation 2 about a facility to occur during an 3 inspection? 4 MR. STANOCH: Objection to 5 form. 6 THE WITNESS: It is -- 7 MR. STANOCH: Beyond the 8 scope. 9 Go ahead. 10 BY MR. HARKINS: 11 Q. You can answer. 12 A. An initial observation 13 occurs frequently at facilities which are 14 inspected by FDA. 15 Q. In your experience how 16 common is it for an initial observation 17 about a facility to relate in some way to 18 cGMP compliance? 19 A. It is -- the observations 20 are made on the basis of evaluation of 21 cGMP compliance. 22 Q. Does such an observation 23 always lead to a recall? 24 A. No, it does not.</p>
---	--

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1 Q. Does such an observation
2 always lead to product being put on hold
3 at that facility?
4 A. No.
5 Q. How, if at all, does such an
6 observation impact other products
7 manufactured at that facility?
8 MR. STANOCH: Objection.
9 THE WITNESS: It does not
10 necessarily impact the facility.
11 BY MR. HARKINS:
12 Q. Does an observation related
13 to cGMPs always cause FDA to determine
14 that all product at a facility is
15 adulterated?
16 MR. STANOCH: Objection to
17 form.
18 THE WITNESS: No.
19 BY MR. HARKINS:
20 Q. Would an observation -- I'm
21 sorry.
22 Does an observation related
23 to cGMPs always cause FDA to determine
24 that a specific product impacted by the

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1 observation is adulterated?
2 A. It may.
3 Q. What would be the
4 implication of Mr. Quick's opinion that
5 all products manufactured at a facility
6 where any cGMP observation occurs is
7 adulterated under the FD&C Act?
8 MR. STANOCH: Objection --
9 objection to form. Misstates
10 testimony and opinion.
11 Go ahead.
12 THE WITNESS: As the former
13 corporate vice president of
14 manufacturing quality of Baxter, I
15 would expect Mr. Quick to know
16 better.
17 BY MR. HARKINS:
18 Q. What do you mean by that?
19 MR. STANOCH: Same
20 objection.
21 THE WITNESS: Mr. Quick was
22 present at the time that a warning
23 letter was awarded to Baxter in
24 the year 2000, in an event that

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1 when asked under deposition, he
2 didn't seem to recall any detail
3 about, although the warning letter
4 that was issued was very specific
5 with respect to one product, and
6 did not indicate anywhere on the
7 warning letter that any other
8 products were affected by it.
9 BY MR. HARKINS:
10 Q. Turning to something else, I
11 remember -- during your testimony today,
12 do you recall being discussed about your
13 knowledge of the legal claims made by
14 plaintiffs in this case?
15 A. I recall being asked about
16 those.
17 Q. Okay. Do you have any
18 knowledge of the specific legal claims
19 made by the class plaintiffs in this
20 case?
21 A. I am not a legal expert. I
22 don't pretend to be a legal expert. I
23 have no knowledge of that; hence, no
24 opinion.

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1 Q. Okay. And you've not been
2 asked to provide any opinions about
3 specific legal theories at issue on this
4 case?
5 A. Not in my report, no.
6 Q. Aside from specific legal
7 theories, do you have a general
8 understanding of the types of harm that
9 are alleged by the class plaintiffs?
10 MR. STANOCH: Objection.
11 Asked and answered.
12 THE WITNESS: So there
13 are -- there are plaintiffs that
14 are alleging injury who are in --
15 as I understand it, seeking a
16 restitution of some kind.
17 BY MR. HARKINS:
18 Q. So does the specific type of
19 harm alleged by the class plaintiffs
20 factor at all to your opinions in this
21 case?
22 A. No, not at all.
23 Q. You spent some time today
24 discussing the Teva and Actavis SOPs that

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1 you reviewed and chose to include at some
2 point as citations in your report.
3 Do you recall that?
4 A. I do.
5 Q. What was your purpose in
6 including those Teva SOPs and Actavis
7 SOPs in your expert report?
8 A. John Quick made reference to
9 the type of matters that form a quality
10 system in a firm, and there -- it stands
11 as a fact that there are standard
12 operating procedures that a company must
13 have in place that govern those
14 meaningful quality system aspects. He
15 mentioned names, as I said, very
16 specifically.
17 And what I thought to do was
18 to request those SOPs from Teva that
19 addressed the same points that Mr. Quick
20 did, though acknowledging, even as he
21 did, this was not intended to be a
22 comprehensive representation of all SOPs
23 that Teva had that govern all these
24 system matters.

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1 Q. You reviewed Mr. Quick's
2 deposition, correct?
3 A. I did.
4 Q. What did he describe insofar
5 as he attempted to review and analyze
6 Teva SOPs in place?
7 MR. STANOCH: Objection.
8 Hold on. Hold on.
9 Objection to form. Outside
10 the scope of the opinions this
11 expert is offering in this case.
12 Go ahead.
13 THE WITNESS: He made the
14 admission in deposition that he
15 did not review SOPs himself. He
16 may have casually passed by
17 documents that involved the topic
18 that are the subject of the SOPs
19 that are cited and the elements of
20 quality systems that he cited, but
21 he said that he didn't review
22 SOPs.
23 BY MR. HARKINS:
24 Q. And just to be

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1 comprehensive, is that the same thing
2 that you saw with respect to Actavis
3 SOPs?
4 A. That is correct.
5 MR. STANOCH: Same
6 objection. Go ahead.
7 (Whereupon, a discussion was
8 held off the record.)
9 (Whereupon, the court
10 reporter read back the requested
11 portions of the transcript.)
12 MR. STANOCH: Same
13 objection.
14 THE WITNESS: Yes.
15 BY MR. HARKINS:
16 Q. Yeah, and Tim, as we go,
17 just try and give him a pause, because
18 he's -- with our incredible technology
19 setup here, you have to give him a moment
20 to make an objection.
21 A. Very well.
22 Q. Given what you saw insofar
23 as Mr. Quick did not analyze Teva or
24 Actavis SOPs, did you feel it was

Page 429

1 necessary to do a fulsome review of those
2 policies to prepare your opinion in this
3 case?
4 MR. STANOCH: Objection to
5 form.
6 THE WITNESS: I reviewed the
7 SOPs to the degree that I needed
8 to make certain that the SOPs were
9 ones that pertained to Teva's
10 quality systems, and they were, by
11 virtue of their identification,
12 ones which would be relevant to my
13 opinion.
14 BY MR. HARKINS:
15 Q. Do you feel that you had
16 sufficient access to Teva's SOPs, and
17 that includes Actavis SOPs, to respond to
18 the statements about quality systems that
19 you saw in Mr. Quick's report?
20 MR. STANOCH: Objection to
21 form.
22 THE WITNESS: Yes.
23 Yes.
24 BY MR. HARKINS:

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1 Q. Turning to a couple of the
2 exhibits that were introduced.
3 Can you go ahead and pull up
4 Exhibit 3 in the DropBox previously
5 introduced.
6 A. Yeah.
7 Q. And this is the "Facts About
8 Current Good Manufacturing Practices"
9 document.
10 A. One moment, please.
11 All right. I have it on the
12 display now.
13 Q. And you said that you are
14 familiar with this document?
15 A. I am.
16 Q. Do you recall being asked if
17 John Quick accurately quoted a line from
18 that document?
19 A. I recall that.
20 Q. And then you testified that
21 that quote did not include what you
22 thought was necessary context; is that
23 accurate?
24 A. That is accurate.

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1 Q. Looking at this exhibit,
2 what is the context in this exhibit that
3 you felt was important?
4 MR. STANOCH: Objection.
5 THE WITNESS: In the section
6 which Mr. Quick cited, the title
7 of the section, "If a manufacturer
8 is not following cGMPs, are drug
9 products safe for use?"
10 Mr. Quick only quoted the
11 very first sentence in this
12 section.
13 But further into this
14 section, there is a context that
15 is relevant for this -- relevant
16 for this understanding here.
17 And if I may read from it, I
18 will quote what that section is
19 here.
20 And that starts at the
21 sentence which reads, "Regulatory
22 actions against companies with
23 poor cGMPs are often intended to
24 prevent the possibility of unsafe

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1 and ineffective drugs.
2 "In rare cases, FDA
3 regulatory action is intended to
4 stop the distribution or
5 manufacturing of violative
6 product.
7 "The impact of cGMP
8 violations depends on the nature
9 of those violations and on the
10 specific drugs involved."
11 BY MR. HARKINS:
12 Q. Without that context which
13 you just now described, how would you
14 describe Mr. Quick's quotation of and use
15 of that single statement that he included
16 in his report?
17 MR. STANOCH: Objection to
18 form.
19 THE WITNESS: It is not
20 true. It is not true because it
21 is not made in context.
22 BY MR. HARKINS:
23 Q. Mr. Anderson, you were asked
24 early on today about a specific statement

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1 in your report where you stated that the
2 cGMP issues identified did not prevent
3 Teva from identifying NDMA or NDEA in the
4 valsartan medication.
5 Do you recall that?
6 A. I do.
7 Q. Do you recall where that
8 statement is in your report?
9 A. I recall the fact that it is
10 in my report. I don't have the immediate
11 knowledge of which paragraph that appears
12 in.
13 Q. Let's go ahead and pull
14 that -- pull your report up.
15 A. Okay.
16 Q. And go to Paragraph 25,
17 where we were discussing this.
18 A. I'm there.
19 Q. Do you see that statement --
20 do you recall discussing this portion of
21 your report, specifically the first
22 clause, which was then combined with the
23 third clause of that sentence during your
24 testimony today?

Page 434

1 MR. STANOCH: Objection to
 2 form.
 3 THE WITNESS: We discussed
 4 the entire -- we discussed the
 5 entirety of this paragraph.
 6 BY MR. HARKINS:
 7 Q. What do you mean by the
 8 statement in this paragraph?
 9 A. What I mean by the statement
 10 is that NDMA and NDEA were not substances
 11 that were either anticipated or predicted
 12 by those who were manufacturers of
 13 valsartan at the time. They were not
 14 predicted by manufacturers of valsartan
 15 drug products at the time.
 16 And FDA readily admits that
 17 NDMA and NDEA were unexpected, by their
 18 telling of it. And in fact, there was --
 19 FDA went so far as to make the statement
 20 that even cGMP evaluations of facilities
 21 would likely not have picked up on NDMA
 22 or NDEA.
 23 Q. And specifically, when you
 24 say that none of the observations by the

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1 FDA nor Teva's own observations prevented
 2 Teva from identifying the NDMA or NDEA
 3 impurities at issue, can you explain that
 4 statement?
 5 MR. STANOCH: Objection.
 6 THE WITNESS: That is a
 7 statement which is -- sorry.
 8 That statement is true on
 9 its face as it appears in my
 10 report. But the context in which
 11 we are speaking here is the global
 12 lack of knowledge and lack of
 13 anticipation that the industry, as
 14 well as regulatory authorities,
 15 had with regard to detection of
 16 NDMA and NDEA.
 17 BY MR. HARKINS:
 18 Q. Regardless of the existence
 19 or nonexistence of any of the
 20 observations identified in Paragraph 25
 21 of your report, what is your opinion
 22 about whether Teva could have identified
 23 NDMA or NDEA impurities in valsartan
 24 medication prior to June 2018?

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1 A. I show in --
 2 MR. STANOCH: Objection to
 3 form.
 4 Go ahead.
 5 THE WITNESS: I show in the
 6 exhaustive exhibit that is part of
 7 this report that there were no
 8 observations that were made,
 9 either by Teva inspectors of
 10 Mylan, Teva inspectors of ZHP,
 11 FDA's inspections of either Mylan
 12 or ZHP, or other health
 13 authorities, namely, the
 14 authorities in the island nation
 15 of Malta, none of the observations
 16 were ones which gave any
 17 indication, spoke of, or any hint
 18 of the presence or potential
 19 presence of either NDMA or NDEA.
 20 BY MR. HARKINS:
 21 Q. And you specifically
 22 mentioned that even FDA had recognized
 23 that it was unlikely cGMP issues -- I'm
 24 sorry -- cGMP inspections would identify

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1 the presence of these impurities?
 2 A. That is correct. I
 3 believe --
 4 MR. STANOCH: Objection to
 5 form.
 6 THE WITNESS: That's
 7 correct. I believe -- I believe
 8 they uttered that opinion soon
 9 after they had set interim
 10 specifications for NDMA and NDEA
 11 presence. I believe it was in
 12 January 2019.
 13 BY MR. HARKINS:
 14 Q. Go ahead and turn to Page 5,
 15 actually of your amended reliance list.
 16 I just want to make sure that I'm talking
 17 about the right document.
 18 MR. STANOCH: Are we talking
 19 about Exhibit 2, Mr. Harkins?
 20 MR. HARKINS: Yeah, and I
 21 want to make sure it's the right
 22 one.
 23 MR. STANOCH: I'm going to
 24 object to this as the reliance

<p>Page 438</p> <p>1 list, because there's a lot of 2 ambiguity on that, which we'll 3 follow up on. But I understand 4 Exhibit 2. 5 MR. HARKINS: It's 6 Exhibit 2, the materials 7 considered. 8 BY MR. HARKINS: 9 Q. Do you see on the bottom of 10 Page 5 the January 2019 statement that 11 you just discussed? 12 A. Page 1, Page 2, Page 3, 13 Page 4, Page 5. And you say that it's at 14 the bottom of Page 5? 15 Q. Fingers crossed. 16 MR. STANOCH: I mean, 17 they're not numbered, and the one 18 on my Page 5 is letter from Malta 19 Medicines. 20 MR. HARKINS: It's middle of 21 Page 6. 22 THE WITNESS: There we are. 23 Entitled "FDA Statement 24 1/25/2019." This is Teva Bates</p> <p>Page 439</p> <p>1 number TEVA-MDL2875-00065839. 2 BY MR. HARKINS: 3 Q. Mr. Anderson, if you can go 4 to the exhibit share and refresh, and 5 pull up what's just been introduced as 6 the most recent exhibit. I believe it's 7 22. 8 (Document marked for 9 identification as Exhibit 10 Anderson-22.) 11 THE WITNESS: I'm there. 12 BY MR. HARKINS: 13 Q. Is this the document that 14 you just identified on the list of 15 materials considered? 16 A. This is the document. 17 Q. Can you identify in this 18 document the statement that you're 19 referring to in our discussion of FDA 20 statements on cGMP inspections and their 21 ability to locate impurities? 22 A. Give me a moment to locate 23 this, please. 24 I have found the paragraph.</p>	<p>Page 440</p> <p>1 It is on the second page of this six-page 2 document. The statement in the -- one, 3 two, three -- third full paragraph on 4 this page at the bottom states, and I 5 quote, "It's unlikely that the subtle 6 problem causing these impurities could 7 have been found on a routine current good 8 manufacturing practice inspection." 9 Q. Thank you, Mr. Anderson. 10 I'd like to turn to another 11 one of the exhibits that was previously 12 introduced. Can you go ahead and, in the 13 exhibit DropBox, reopen Exhibit 4. 14 A. It's open. 15 Q. And this is the e-mail from 16 Mr. Nassall to some folks at ZHP. You 17 recall discussing this e-mail, correct? 18 A. I do. 19 Q. Why do you discuss this 20 document in your report? 21 A. I discuss this document only 22 because it was something that was -- a 23 situation that was referenced in John 24 Quick's report, and the characterizations</p> <p>Page 441</p> <p>1 and what I felt were unfair implications 2 that Mr. Quick was making about the 3 dialogue with respect to ZHP's 4 cooperation with an inquiry that was 5 being made by Teva. 6 Q. I -- to confirm, you don't 7 have any opinion or knowledge about 8 whether this is the first time anyone at 9 Teva learned of this document? I believe 10 you testified to that. 11 MR. STANOCH: Objection to 12 form. 13 THE WITNESS: I testified 14 that I did not -- I'm sorry. 15 I testified that I did not 16 know necessarily that this was the 17 first notification that Teva as a 18 company had. 19 BY MR. HARKINS: 20 Q. You didn't have any basis to 21 confirm or deny that, right? 22 A. Correct. 23 Q. That would be outside the 24 scope of the expert report and opinion</p>
--	--

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1 that you were asked to provide in this
2 case?
3 A. I agree.
4 Q. Turn back to the list of
5 materials considered for just a moment.
6 Did you review all of the
7 certificates of analysis that are
8 identified on your list of materials
9 considered?
10 A. I reviewed them --
11 MR. STANOCH: Objection.
12 Asked and answered.
13 Go ahead.
14 THE WITNESS: I reviewed and
15 considered them.
16 BY MR. HARKINS:
17 Q. What did you review and how
18 did your review and consideration of
19 those factor into your opinions in this
20 case?
21 A. The certificates of analysis
22 that I reviewed had no evidence that any
23 testing was done in the context of NDMA
24 or NDEA for information purposes or

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1 against a specification of any kind
2 appearing on the certificates.
3 Q. What in those certificates
4 of analysis did you feel it was necessary
5 to affirmatively cite to in your expert
6 report?
7 A. The fact that the --
8 MR. STANOCH: Objection to
9 form. Asked and answered.
10 Go ahead.
11 THE WITNESS: The fact that
12 the certificates of analysis
13 contained data on them that shows
14 that they conform to
15 specifications that were present
16 on the certificates of analysis.
17 BY MR. HARKINS:
18 Q. Do you feel it was necessary
19 to include specific citations to each of
20 these certificates of analysis in your
21 expert report?
22 MR. STANOCH: Objection.
23 THE WITNESS: I do not.
24 BY MR. HARKINS:

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1 Q. You were also asked just a
2 little while ago, technical issues
3 notwithstanding, about the 2019
4 inspection by the FDA of Teva's OSD
5 facility in Jerusalem.
6 Do you recall that?
7 A. I do recall that.
8 Q. Do you recall being told
9 that that inspection was about valsartan?
10 MR. STANOCH: Objection to
11 form.
12 THE WITNESS: I recall that.
13 BY MR. HARKINS:
14 Q. Do you recall the questions
15 about why you didn't consider this
16 inspection report in forming your opinion
17 in this case?
18 A. I recall being questioned
19 about that.
20 Q. Do you recall being asked
21 whether you reviewed the results of the
22 inspection that purportedly related to
23 valsartan?
24 A. I recall being asked that.

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1 Q. Were you shown the
2 inspection report during that
3 questioning?
4 A. I was not shown it.
5 Q. You were just shown notes
6 about the inspection, which it does have
7 a mention of valsartan being discussed,
8 right?
9 A. The notes mentioned
10 valsartan being discussed.
11 Q. Please reload the DropBox
12 and open what is introduced as Exhibit
13 Number 23.
14 (Document marked for
15 identification as Exhibit
16 Anderson-23.)
17 THE WITNESS: I'm there.
18 BY MR. HARKINS:
19 Q. Scroll down past the first
20 page. And take a look at this document.
21 Take as long as you need.
22 Have you seen this document
23 before?
24 A. No, I have not.

<p style="text-align: right;">Page 446</p> <p>1 Q. And again, take as long as 2 you need to familiarize, understanding 3 that. 4 What is this document? 5 A. This document is a Form 483 6 that was issued in accordance with an 7 inspection that occurred in Israel at 8 Teva Pharmaceuticals Industry in 9 Jerusalem on the dates of July 28th 10 through August 1st, 2019. 11 Q. And again, take as long as 12 you need to familiarize yourself with 13 this document. 14 Does this appear to be the 15 483 that the FDA sent in connection with 16 the 2019 inspection that you were asked 17 about by plaintiffs' counsel? 18 A. Let me just have a look at 19 it from top to bottom. 20 There are four observations 21 which appear here, and I've made familiar 22 with the fact that there were four 23 observations which proceeded from this 24 inspection from the document that</p>	<p style="text-align: right;">Page 448</p> <p>1 second page, and I'd like you to identify 2 for me what drug substances are discussed 3 on the second page of this 483? 4 A. Give me a moment to review. 5 The products that are named 6 in Observation 2 are imatinib mesylate, 7 clonazepam, clozapine, divalproex sodium, 8 and atorvastatin. 9 Q. And is there any mention on 10 this page about valsartan or any other 11 sartan products? 12 A. The word "valsartan" does 13 not appear anywhere in Observation 2. 14 Q. Is there any discussion on 15 this page of the 483 of NDMA, NDEA, or 16 any nitrosamines whatsoever? 17 A. Not at all. 18 Q. Go to the next page. And 19 again, sir, I'm just going to ask you to 20 review this, again looking for the 21 products that are identified and any 22 mention of nitrosamines, and let me know 23 whenever you're finished. 24 A. I do not see the word</p>
<p style="text-align: right;">Page 447</p> <p>1 Mr. Stanoch provided. 2 Q. Okay. Does this appear to 3 be the 483 that relates to that 4 inspection? 5 A. It does. 6 Q. Go ahead and look at just 7 the first substantive page on this 483. 8 And understanding that you have not seen 9 this document before, I'd like you to go 10 ahead and review it and identify on the 11 first page where it mentions valsartan? 12 A. Give me a moment. I've read 13 Observation 1. I do not see the word 14 "valsartan" anywhere in it. 15 Q. Do you see a mention of any 16 other sartan medication? 17 A. I do not. 18 Q. Do you see any mention of 19 NDMA, NDEA, or any nitrosamines? 20 A. Those abbreviations do not 21 appear in this observation. 22 Q. Please go to the second 23 page. 24 Go ahead and review the</p>	<p style="text-align: right;">Page 449</p> <p>1 "valsartan" anywhere in Observation 3. I 2 see no mention of anything having to do 3 with detection of NDMA or NDEA. 4 Q. Go to the next page of the 5 document. Take your time to review it 6 since you're seeing it for the first 7 time. 8 Let me know if you see any 9 mention of valsartan or any other sartan 10 medication or nitrosamines. 11 A. Okay. To be clear, the top 12 of this page is a continuation of the 13 third observation. 14 So I'm going to comment 15 first on the context of Observation 3, 16 and will continue on to observation four, 17 which also itself continues on to the 18 following page. So I'll separate my 19 observation in that context. 20 Q. Sure. 21 A. Finishing my comment with 22 respect to Observation 3, again, there is 23 no mention of valsartan or of anything 24 having to do with NDMA or NDEA.</p>

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1 Continuing now onto
2 Observation 4. It begins on this page.
3 I will comment on the whole observation,
4 once I have completed reading it.
5 Q. Sure.
6 Let me know when you're done
7 reading this part of it and we'll turn to
8 the next page, and then I'll ask you
9 question. Okay?
10 A. Very well.
11 On this first portion of
12 Observation 4 which appears on Page 5 of
13 7 in this document, but named as Page 4
14 of 5 on the 483, there is no mention of
15 the word "valsartan" or anything having
16 to do with NDMA or NDEA.
17 Q. And then turning to the
18 final page, once again, I'll just ask you
19 to review, take as much time as you need.
20 And ask you do you see any
21 reference on this final page at the end
22 of Observation 4 with respect to
23 valsartan, any other sartan medication,
24 or NDMA, NDEA, or nitrosamines?

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1 A. There is no mention of
2 valsartan on this page, nor is there any
3 mention of NDMA or NDEA in the final
4 observations for Observation Number 4.
5 Q. And just scroll down to the
6 last page, which appears to be some sort
7 of boilerplate language, but I just want
8 to confirm.
9 The same applies with
10 respect to this nonsubstantive page?
11 A. This is nonsubstantive and
12 is something which is a part of every 483
13 as it refers to various sections of the
14 FD&C and the U.S.C.
15 Q. Mr. Anderson, did you see
16 anything in this 483 that pertains to
17 valsartan or any other sartan medication?
18 A. Not a thing.
19 Q. Do you see anything in this
20 Form 483 that pertains to NDMA, NDEA, or
21 any other nitrosamine?
22 A. Not a thing.
23 Q. Is there anything in this
24 document that would change your opinions

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1 in this case that you rendered in your
2 expert report on January 12th?
3 A. Not at all.
4 Q. Do you find anything in this
5 document to be relevant to the opinions
6 that you rendered in your expert report
7 submitted on January 12th?
8 A. Not relevant at all, the
9 reason being, this 483 not only does not
10 contain anything having to do with the
11 topic of valsartan or the NDMA/NDEA
12 impurity matter, but it is also something
13 that was issued at a time long past the
14 time that Teva ceased to be marketing
15 valsartan products.
16 Q. And just to confirm, because
17 I don't know that we really squarely
18 addressed it yet today, what is your
19 conclusion from your review of material
20 that you looked at to prepare your expert
21 report in this case as to whether any of
22 Teva's valsartan or valsartan-containing
23 products was adulterated under the terms
24 of the FD&C Act?

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1 MR. STANOCH: Objection to
2 form.
3 THE WITNESS: The valsartan
4 products, as they were made, were
5 declared -- or the APIs
6 declared -- was declared as
7 adulterated as of November 29,
8 1918 and not a time before that.
9 BY MR. HARKINS:
10 Q. Sorry about that. 2018?
11 A. I'm sorry. Forgive me.
12 Scratch that year. More correctly, it's
13 2018. Yes.
14 Q. You reviewed a significant
15 number of documents, both in preparing
16 your report and in preparing to come in
17 and take your deposition today?
18 A. Yes. And among those
19 documents were included the actual
20 inspection reports that were prepared by
21 Teva auditors as well as the 483s which
22 were issued by FDA or by the Maltese
23 inspection authority.
24 Q. And those -- that's the

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1 material that you discuss, not only in
2 the body of your report but in your
3 detailed appendix?
4 A. I discuss this extensively
5 in the detailed appendix, which captures
6 all of the observations that were made in
7 all of these inspections and with
8 responses that were prepared by the -- by
9 Mylan or by ZHP or by Teva, depending on
10 what the nature of the audit or
11 inspection was.
12 Q. Have you seen anything
13 during your review of materials in
14 preparation to coming for your deposition
15 today that's caused you to change your
16 opinions as set forth in your January 12,
17 2022 report?
18 MR. STANOCH: Objection to
19 form.
20 THE WITNESS: Not a thing.
21 BY MR. HARKINS:
22 Q. Have you been shown anything
23 by plaintiffs' counsel during the
24 deposition today that has caused you to

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1 change any of your opinions set forth in
2 your January 12, 2022 expert report?
3 MR. STANOCH: Same
4 objection.
5 THE WITNESS: Not a thing.
6 MR. HARKINS: Thank you,
7 Tim.
8 Those are all the questions
9 I have.
10 THE WITNESS: Thank you all
11 for your time.
12 MR. HARKINS: He may have
13 more for you.
14 MR. STANOCH: I do not. No
15 questions. We're done.
16 MR. HARKINS: Anything from
17 anyone else?
18 All right. Thanks everyone,
19 and sincere apologies. Let's go
20 off the record.
21 THE VIDEOGRAPHER: The time
22 is 7:41 p.m. We are off the
23 record.
24

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1 *****
2 (Excused.)
3 (Deposition concluded at
4 approximately 7:41 p.m.)
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1
2 CERTIFICATE
3
4
5 I HEREBY CERTIFY that the
6 witness was duly sworn by me and that the
7 deposition is a true record of the
8 testimony given by the witness.
9
10 It was requested before
11 completion of the deposition that the
12 witness, TIMOTHY A. ANDERSON, M.S., MBA,
13 have the opportunity to read and sign the
14 deposition transcript.
15
16 MICHELLE L. GRAY,
17 A Registered Professional
18 Reporter, Certified Shorthand
19 Reporter, Certified Realtime
20 Reporter and Notary Public
21 Dated: March 11, 2022
22
23 (The foregoing certification
24 of this transcript does not apply to any
reproduction of the same by any means,
unless under the direct control and/or
supervision of the certifying reporter.)

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INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it.

You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

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E R R A T A
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PAGE LINE CHANGE

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ACKNOWLEDGMENT OF DEPONENT

I, _____, do hereby certify that I have read the foregoing pages, 1 - 461, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

TIMOTHY A. ANDERSON, M.S., MBA DATE _____

Subscribed and sworn to before me this _____ day of _____, 20____.

My commission expires: _____

Notary Public

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LAWYER'S NOTES

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Exhibit 214

REDACTED

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF NEW JERSEY
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5 *****

6 IN RE: VALSARTAN, LOSARTAN,
7 AND IRBESARTAN PRODUCTS MDL No. 2875
8 LIABILITY LITIGATION
9

9 *****

10 THIS DOCUMENT APPLIES TO ALL
11 CASES

HON. ROBERT B. KUGLER

12 *****

13

14 - CONFIDENTIAL INFORMATION -

15 SUBJECT TO PROTECTIVE ORDER
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20 Remote videotaped deposition of
21 STEVEN BAERTSCHI, Ph.D., commencing
22 at 9:09 a.m. EST, on the 23rd of March,
23 2022.
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<p style="text-align: right;">Page 10</p> <p>1 VIDEOGRAPHER: 2 We are now on the record. 3 My name is Jeff Fleming. I'm a 4 videographer for Golkow Litigation Services. 5 Today's date is March 23rd, 2022. Time 6 is 9:09 a.m. 7 This remote video deposition is being 8 held in the matter of Valsartan, Losartan, and 9 Irbesartan Products Liability litigation, in the 10 United States District Court, District of New 11 Jersey. 12 The deponent is Dr. Steven Baertschi. 13 All parties to this deposition are 14 appearing remotely and have agreed to the witness 15 being sworn in remotely. Due to the nature of 16 remote reporting, please pause briefly before 17 speaking to ensure all parties are heard 18 completely. 19 Appearances will be noted on the 20 stenographic record. 21 The court reporter is Lois Robinson, 22 who will now swear in the witness. 23 STEVEN BAERTSCHI, Ph.D., 24 the witness, after having first been</p>	<p style="text-align: right;">Page 12</p> <p>1 What cases? 2 A Um, I don't have that committed to 3 memory, but they were all patent disputes between 4 two pharmaceutical companies. 5 Q And over what -- do you remember what 6 party hired you for those cases? 7 A Can I look at my CV to remember? 8 Q Sure. 9 MR. HARKINS: 10 He has a copy of the original report. 11 It also has a CV attached as an exhibit. 12 So, Doctor, you can look at that. 13 A One -- the most recent one was for 14 Exel- -- for Eton Pharmaceuticals versus Exela. 15 A previous one, that was not a 16 deposition, so I'll skip that. 17 Then there -- 18 Well, no. There was -- so that was 19 Mylan versus Teva. 20 MS. BOGDAN: 21 Q Okay. And, Doctor, could you tell me 22 what part of your CV you're looking at to refresh 23 your recollection with regard to my question? 24 A The very end. The very last page on my</p>
<p style="text-align: right;">Page 11</p> <p>1 duly sworn to tell the truth, the whole truth, 2 and nothing but the truth, was examined and 3 testified as follows: 4 EXAMINATION 5 BY MS. BOGDAN: 6 Q Good morning, Dr. Baertschi. Did I 7 pronounce your name correctly? 8 A It's Baertschi, like bear and cheese. 9 Yes. 10 Q Okay. Good morning. My name is 11 Rosemarie Bogdan, and I'm a member of the 12 Plaintiffs' Steering Committee in this 13 litigation. I'm going to be asking you some 14 questions today. And my first question for you 15 is have you ever been deposed before? 16 A Yes. 17 Q Okay. And how many times have you been 18 deposed? 19 A Three or four. I think it's three, but 20 it might be four. 21 Q And how many of those were in a 22 litigation context? 23 A All of them. 24 Q And what matters were you deposed on?</p>	<p style="text-align: right;">Page 13</p> <p>1 CV. 2 Q And when you said -- you first spoke of 3 the Exela versus Eton Pharmaceutical case. 4 A Yes. 5 Q Which party were you hired by? 6 A Eton. 7 Q And then I believe you just referenced 8 a Mylan versus Teva case? 9 A Yeah, and I -- yes. 10 Q Which -- 11 A But I actually don't think -- I don't 12 think I was deposed in that record. 13 MR. HARKINS: 14 Let her finish her question. Okay? 15 MS. BOGDAN: 16 Q And which party did you represent or 17 you were retained by in that case? 18 A Mylan. 19 Q Okay. And the last matter? 20 A Last matter was a number of companies. 21 There were eleven companies represented by eleven 22 legal firms. I think I was originally hired by 23 Mylan in that case versus Takeda and AstraZeneca. 24 Q Now, prior to being hired as an expert</p>

<p style="text-align: right;">Page 14</p> <p>1 by Mylan in the two litigations that you've 2 testified that you were retained, had you worked 3 for Mylan as a consultant? 4 A No. 5 Q Prior to being retained in this 6 litigation, have you worked for Teva as a 7 consultant? 8 A No. 9 Q Now, with regard to the Exela Pharma 10 versus Eton Pharmaceutical case, that's one that 11 you recently testified in; correct? 12 A Yes. 13 Q Okay. And that was -- 14 Okay. And when did you testify in that 15 case? 16 A Last Tuesday. Last week. 17 Q And did you testify more than once in 18 that case? 19 A I was deposed twice, and I testified 20 once. 21 Q So when you say "deposed," you mean at 22 a deposition? 23 A Yes. 24 Q When you say "testified," do you mean</p>	<p style="text-align: right;">Page 16</p> <p>1 posing, that you please let me know that so I 2 have an opportunity to rephrase it for you. Is 3 that acceptable to you? 4 A That is acceptable. 5 Q If you answer a question, I'm gonna 6 assume that you understand what I'm asking. 7 Okay? 8 A Okay. 9 Q And because we're doing this remotely, 10 it becomes particularly important -- and I 11 believe the stenographer reminded both of us -- 12 if we don't talk over each other. So sometimes 13 there's a little bit of a delay on the video, 14 et cetera. 15 So if -- I'm going to try to make sure 16 that you're done with your answer before I start 17 my next question. And if you could just wait a 18 little bit to make sure I'm done with my question 19 before you start to answer. Okay? 20 A Okay. 21 Q Now, have you met -- 22 Sorry. There was a little glitch here 23 on the audio. 24 What did you do to prepare for your</p>
<p style="text-align: right;">Page 15</p> <p>1 in a court proceeding? 2 A Yes. 3 Q Now, in that case, wasn't your 4 testimony precluded with regard to your 5 noninfringement positions by court order? 6 A It was -- there was a preclusion of 7 part of what I testified about due to a legal 8 dispute on the interpretation of the law between 9 the two legal firms, which the judge made a 10 ruling on just prior to trial. So one small part 11 of my testimony was precluded, yes. 12 Q When you say "precluded," that meant 13 that the Court would not allow you to testify 14 about that particular part of your opinion at the 15 trial of the matter; correct? 16 MR. HARKINS: 17 Objection to the extent it calls for a 18 legal conclusion. 19 You can answer. 20 A As I understand it, yes. 21 MS. BOGDAN: 22 Q I'm going to be asking you questions 23 today, and what I would like to ask of you is if 24 you don't understand the question that I'm</p>	<p style="text-align: right;">Page 17</p> <p>1 deposition today? 2 A Can I ask this question? Can I change 3 my display so it doesn't flip like we have it so 4 I don't see the large screen of whoever's 5 speaking? I'd just rather see the gallery, 6 because it's disruptive to me in my thinking when 7 the -- when the feed flips pictures. 8 Q Why don't we just go off the record so 9 they can make that adjustment for you in the 10 room. I don't think it's something that the 11 videographer or I can do. So let's just go off 12 the record, and maybe Mr. Harkins can help you 13 with that setting. 14 VIDEOGRAPHER: 15 Off record, 9:19 a.m. 16 (OFF THE RECORD.) 17 VIDEOGRAPHER: 18 On record, 9:23 a.m. 19 MS. BOGDAN: 20 Q Dr. Baertschi, I believe before we went 21 off the record to deal with that technical issue, 22 my question that I asked you was what did you do 23 to prepare for your deposition here today? 24 A Yes. I reviewed my expert report, some</p>

<p style="text-align: right;">Page 18</p> <p>1 of the references -- on my own I did this -- some 2 of the references that I refer to in the expert 3 report. I had a preparative meeting with Steve 4 Harkins on Friday for a couple of hours. I had 5 another preparative meeting for a couple of 6 hours -- 7 Wait. On Friday, yes. 8 And then I had another preparative 9 meeting on Monday for a couple of hours with 10 Steve Harkins, and then I spent all day or about 11 eight hours yesterday with both Steve Harkins and 12 Tori Langton. 13 Q So you mentioned a bunch of different 14 preparatory meetings. How many hours did you 15 spend in preparatory meetings? 16 A Twelve to 15. 17 Q And as far as your document review, you 18 said you reviewed your report? 19 A Yes. 20 Q Did you review any other specific 21 documents? 22 A Yes. I went through some of the 23 documents to refresh my memory. I can't remember 24 all of them. But, more explicitly, the ones that</p>	<p style="text-align: right;">Page 20</p> <p>1 references that I specifically quote or 2 specifically call out versus I might have some 3 references where there's one, two, three, four, 4 five, six references to a particular statement I 5 make. I didn't necessarily go look at all of 6 those. 7 MS. BOGDAN: 8 Q And was it that review that prompted 9 the corrected report that I received yesterday, 10 which was March 22nd? 11 A Yes. 12 Q And did you substantively change 13 anything in the report with regard to your 14 opinions in this matter? 15 A No. 16 Q Just changed reference cites, 17 essentially? 18 A I changed errors that I had made in 19 referencing the wrong article, and I also had a 20 couple of numbers that I had copied wrong when I 21 made a grammatical -- not a grammatical -- 22 copy/paste error looking at -- 23 I mean, if you want to go through each 24 one, I can specifically tell you. But it was</p>
<p style="text-align: right;">Page 19</p> <p>1 were cited in my report where I quoted from them, 2 I kind of went back to those reports and took a 3 look to refresh my memory. 4 Q So you reviewed the documents that are 5 actually cited as references in your report? 6 A Yes. 7 Q That you specifically have in your 8 report on pages 25, 26, and 27? 9 MR. HARKINS: 10 And, just for clarity, Rosemarie, is 11 this the original report or the corrected report? 12 MS. BOGDAN: 13 I don't believe it makes a difference, 14 actually, but the corrected report. 15 MR. HARKINS: 16 So, Dr. Baertschi, the 3-22 date on it, 17 just to make sure your pages are exact. 18 A Yes. I'm looking at 25, 26, and 27, 19 and it looks like a list of references 1 through 20 32. I'm not saying that I went through all of 21 those references. I looked at them all, the 22 reference, just like on this page, and decided 23 which ones to kind of go actually pull up and 24 reread. And that was partially guided by</p>	<p style="text-align: right;">Page 21</p> <p>1 reference error, like I lost track of which 2 reference I was -- 3 And then I -- I found that when I went 4 in to look at the articles that, oh, I have got 5 now the wrong reference for the quotation, and I 6 copied the wrong number for a threshold. 7 Q One of the changes you made was with 8 regard to the number of peer-reviewed articles 9 you authored? 10 A Yes. I think when I had submitted the 11 CV, there was one article that was in press -- 12 not in press. It was -- I expected it to be 13 submitted before -- 14 This was a while ago. And I just never 15 paid attention to -- 16 It hasn't still yet been submitted. 17 And when I testified last week, they asked me the 18 question how many peer-reviewed, and I had just 19 looked at it, and I remembered 58. And then when 20 I looked in my CV -- not my CV -- I looked at 21 this expert report and it said 59, and I said 22 it's 58. And I looked and confirmed. So I had 23 made a -- an error on the numbers that I counted. 24 Q So you counted one of the articles that</p>

<p style="text-align: right;">Page 22</p> <p>1 you authored as a peer-reviewed article that had 2 not yet been peer-reviewed; correct? 3 A Correct. 4 Q With regard to the citation corrections 5 that you made, did you add any new citations to 6 the report? 7 A No. 8 Q So it was a matter of actually 9 assigning the right article to the right quote? 10 A Yes. That's my recollection. That's 11 what I -- yes. 12 Q Did you bring any documents with you 13 today? 14 A No. There's -- the only documents I 15 have are what's been provided by Steve Harkins. 16 Q Okay. And what documents are those 17 that you have? Do you have documents sitting in 18 front of you? I'm not in the room, so I can't -- 19 I can't see. 20 A Yes. I have my expert report and my 21 corrected expert -- the pre-corrected expert 22 report, along with my CV and my corrected expert 23 report, and I have a list of materials 24 considered. I don't know if you need me to hold</p>	<p style="text-align: right;">Page 24</p> <p>1 Q Okay. And in the room with you today, 2 is there anyone in the room with you today other 3 than Attorney Harkins and Attorney Langton? 4 A No. 5 Q If we could please pull up the notice 6 to take the videotaped oral deposition as an 7 exhibit, please. 8 MR. HARKINS: 9 And, Dr. Baertschi, just so you're used 10 to this now, in a moment you're gonna refresh 11 that just to make sure the Dropbox is working 12 appropriately for you. But you can review it on 13 the hard copy or electronic copy. 14 THE WITNESS: 15 Okay. I can see it on this screen. 16 I'm not seeing anything here. It says no file. 17 Should I say download all files? 18 MR. HARKINS: 19 Rosemarie, is that being introduced 20 or -- 21 MS. BOGDAN: 22 I'm gonna mark it. I'm going to 23 introduce it. If the doctor can see it on the 24 computer screen right in front of him --</p>
<p style="text-align: right;">Page 23</p> <p>1 these up. 2 I have a notice to take videotaped oral 3 deposition, and I have a defendant's responses 4 and objections to plaintiffs' notice. 5 Q Okay. Do you have anything else other 6 than what you've just listed off? 7 A I have a cell phone that I have turned 8 off or silenced. I have a pen, and I have a pad 9 of paper that's empty. 10 Q I meant documents. 11 A Oh. No. 12 Q Like -- I'll ask you about electronic 13 devices. Now, I'm assuming you're speaking to me 14 through some type of computer or, you know, 15 audiovisual system. On that computer, is there 16 any email or direct message or chat that you're 17 using? 18 A No. 19 Q All right. So all applications right 20 now are off and will remain off during the course 21 of the deposition? 22 A Yes. And I don't have -- it's not my 23 computer. It's a loaner computer from Greenberg 24 Traurig, so that it's clean.</p>	<p style="text-align: right;">Page 25</p> <p>1 THE WITNESS: 2 I've got it up now on both screens, but 3 it's -- 4 MS. BOGDAN: 5 Q Okay. Yeah. 6 A -- it's clearer on this screen. 7 Q Okay. I believe the way this is 8 supposed to work is they should match at all 9 times. If they don't match, you definitely let 10 us know. Okay? 11 A Okay. 12 Q If we could mark the notice to take 13 videotaped deposition as exhibit -- 14 Are we going to use numbers today? 15 One. 16 MR. HARKINS: 17 That sounds good to me. 18 (DEPOSITION EXHIBIT NUMBER 1 19 WAS MARKED FOR IDENTIFICATION.) 20 MS. BOGDAN: 21 Q All right. Doctor, is this the notice 22 that you referred to having with you today in the 23 room? 24 MR. HARKINS:</p>

<p style="text-align: right;">Page 26</p> <p>1 The notice, not the objections.</p> <p>2 A Yes.</p> <p>3 MS. BOGDAN:</p> <p>4 Q Okay. Do you see the document requests</p> <p>5 that are a part of that notice on the third page?</p> <p>6 A Yes.</p> <p>7 Q Were you provided that list of document</p> <p>8 requests?</p> <p>9 A Yes.</p> <p>10 Q Did you go about assembling responses</p> <p>11 to those requests?</p> <p>12 A Yes. I -- I had a con- -- conversation</p> <p>13 with Steve, and we went through all of these, and</p> <p>14 I provided everything that I could that was</p> <p>15 related that -- based on advice of counsel.</p> <p>16 MS. BOGDAN:</p> <p>17 If we could mark the defendant's</p> <p>18 responses and objections to plaintiffs' notice.</p> <p>19 A Yes. I'm sorry. Could you repeat</p> <p>20 that? Did you say do you mark?</p> <p>21 Q No. I'm sorry. I was asking the court</p> <p>22 reporter to bring up the next exhibit, please,</p> <p>23 and please mark this as Exhibit 2.</p> <p>24 (DEPOSITION EXHIBIT NUMBER 2</p>	<p style="text-align: right;">Page 28</p> <p>1 A I really don't know. I -- I might</p> <p>2 know, but I'm uncertain with the question and</p> <p>3 uncertain with...</p> <p>4 MS. BOGDAN:</p> <p>5 Q Did you see a copy of the file for you</p> <p>6 that was produced in this litigation?</p> <p>7 A Probably. But it's escaping my memory</p> <p>8 right now. But I was probably made aware of</p> <p>9 that.</p> <p>10 Q There was a file produced for you in</p> <p>11 litigation on Monday of this week. Were you</p> <p>12 provided a copy of that file?</p> <p>13 A I'm pretty sure I was. I think I was.</p> <p>14 MR. HARKINS:</p> <p>15 Don't -- don't assume if you're unsure.</p> <p>16 A I'm unsure. I really don't know for</p> <p>17 sure.</p> <p>18 MS. BOGDAN:</p> <p>19 Q So you don't know if you have received</p> <p>20 a copy of the documents that were produced on</p> <p>21 your behalf in prep- -- two days ago --</p> <p>22 A Yeah.</p> <p>23 Q -- in response to this notice that was</p> <p>24 marked as Exhibit 1?</p>
<p style="text-align: right;">Page 27</p> <p>1 WAS MARKED FOR IDENTIFICATION.)</p> <p>2 MS. BOGDAN:</p> <p>3 Q And, Dr. Baertschi, is what's been</p> <p>4 marked as Exhibit 2 the defendant's responses and</p> <p>5 objections to the plaintiffs' notice that you</p> <p>6 mentioned that you have with you today?</p> <p>7 A Yes. Yes.</p> <p>8 Q And have you read that document?</p> <p>9 A Yes.</p> <p>10 Q And, to your knowledge, did you provide</p> <p>11 to counsel all of the documentation that you had</p> <p>12 that was responsive to the demands?</p> <p>13 A Well, I responded with everything that</p> <p>14 counsel suggested or discussed with me that I</p> <p>15 should provide, based on his objections or the</p> <p>16 company's objections and what's appropriate to</p> <p>17 provide.</p> <p>18 Q And were all those things that were</p> <p>19 appropriate to provide included in your file that</p> <p>20 was produced?</p> <p>21 MR. HARKINS:</p> <p>22 Object to form. Calls for a legal</p> <p>23 conclusion.</p> <p>24 You can answer, to the extent you know.</p>	<p style="text-align: right;">Page 29</p> <p>1 A I'm sorry. My memory is so full from</p> <p>2 going over so much material, and I don't recall</p> <p>3 for sure whether I received an email notice</p> <p>4 with -- with the information, the response. I</p> <p>5 have -- I was explained -- it was -- I -- I did</p> <p>6 discuss what materials --</p> <p>7 MR. HARKINS:</p> <p>8 Just -- do not discuss anything that</p> <p>9 reflects conversations that you had with me or</p> <p>10 any other counsel. But you can answer, again, to</p> <p>11 the extent you understand, what, if anything, was</p> <p>12 produced.</p> <p>13 A I'm not sure what -- if I got a notice</p> <p>14 or not.</p> <p>15 MS. BOGDAN:</p> <p>16 Q Well, as you sit here today, you can't</p> <p>17 tell me if the documents that were produced</p> <p>18 included all of the documents that you provided</p> <p>19 to counsel that were responsive to the demands?</p> <p>20 A As I sit here today, I cannot remember</p> <p>21 if I was sent a notification via email of that.</p> <p>22 Q Do you have any notes in front of you</p> <p>23 today?</p> <p>24 A No.</p>

<p style="text-align: right;">Page 30</p> <p>1 MS. BOGDAN:</p> <p>2 If we could please mark the first</p> <p>3 expert report with exhibits that was produced by</p> <p>4 the doctor.</p> <p>5 (DEPOSITION EXHIBIT NUMBER 3</p> <p>6 WAS MARKED FOR IDENTIFICATION.)</p> <p>7 MS. BOGDAN:</p> <p>8 Q Has that been marked as Exhibit 3?</p> <p>9 TRIAL TECH:</p> <p>10 Yes.</p> <p>11 MS. BOGDAN:</p> <p>12 Q Doctor, can you see what's been marked</p> <p>13 as Exhibit 3?</p> <p>14 A I can see it on this screen, and now I</p> <p>15 can see it on a big screen. So, yes.</p> <p>16 Q Is that your first expert report with</p> <p>17 exhibits that was produced in this litigation?</p> <p>18 A I will have to find where -- I will</p> <p>19 have to go to where one of those changes were</p> <p>20 made to -- to figure out whether or not --</p> <p>21 Okay. It looks like it, because I see</p> <p>22 that I reference 59 peer-reviewed articles. So</p> <p>23 it must not be the corrected version. So it must</p> <p>24 be the first version.</p>	<p style="text-align: right;">Page 32</p> <p>1 If we could please pull up as Exhibit 5</p> <p>2 and mark the amended list of materials</p> <p>3 considered.</p> <p>4 (DEPOSITION EXHIBIT NUMBER 5</p> <p>5 WAS MARKED FOR IDENTIFICATION.)</p> <p>6 A I see it.</p> <p>7 MS. BOGDAN:</p> <p>8 Q And, Doctor, is this a copy of your</p> <p>9 amended list of materials considered that was</p> <p>10 served on March 21st, 2022?</p> <p>11 A Yes.</p> <p>12 Q What did you amend regarding your</p> <p>13 materials considered list between the original</p> <p>14 one that was served and this one?</p> <p>15 A There were some depositions I know that</p> <p>16 were added that weren't available at the time.</p> <p>17 And I don't remember everything that was amended.</p> <p>18 Q So you remember that depositions in</p> <p>19 general were added that weren't available at the</p> <p>20 time of your original list of materials</p> <p>21 considered?</p> <p>22 A That's my memory, yes.</p> <p>23 Q Did you add any research articles or</p> <p>24 studies to this amended list of materials</p>
<p style="text-align: right;">Page 31</p> <p>1 MS. BOGDAN:</p> <p>2 All right. And, then, if we could</p> <p>3 please pull up the corrected expert report and</p> <p>4 mark that as the next exhibit, Exhibit 4.</p> <p>5 (DEPOSITION EXHIBIT NUMBER 4</p> <p>6 WAS MARKED FOR IDENTIFICATION.)</p> <p>7 A Is there a question?</p> <p>8 MS. BOGDAN:</p> <p>9 Q And, Doctor, can you see Exhibit 4 now</p> <p>10 on your screen? And my question would be: Is</p> <p>11 that a copy of your corrected report that was</p> <p>12 served March 22nd, 2022?</p> <p>13 A I can see it. I'm check- -- I'm</p> <p>14 scrolling down to the point where I see I have</p> <p>15 authored 58 peer-reviewed articles, which</p> <p>16 suggests to me that this is the revised expert</p> <p>17 report.</p> <p>18 Q And on the first page of that exhibit,</p> <p>19 it actually has the date of March 22nd, 2022.</p> <p>20 A I see that.</p> <p>21 Q Okay. And does that also indicate it's</p> <p>22 your corrected expert report?</p> <p>23 A Yes.</p> <p>24 MS. BOGDAN:</p>	<p style="text-align: right;">Page 33</p> <p>1 considered?</p> <p>2 A I do not believe so. I --</p> <p>3 Can I correct that? I see two articles</p> <p>4 that I co-authored at the bottom of -- well, it's</p> <p>5 at the bottom of page 10 that I don't think were</p> <p>6 in the original list but are -- are in this list.</p> <p>7 So I think there are maybe -- there's at least</p> <p>8 those two articles that were added.</p> <p>9 Q Which two articles are those?</p> <p>10 A The last two on page 10. They're 2018</p> <p>11 and 2013.</p> <p>12 Q The -- I believe if you could --</p> <p>13 A I believe --</p> <p>14 I'm sorry.</p> <p>15 MS. BOGDAN:</p> <p>16 If we could just highlight those.</p> <p>17 Q "The Artificial Degradation of</p> <p>18 Secondary Amine," that article?</p> <p>19 A Yes. I think these were added, to the</p> <p>20 best of my recollection.</p> <p>21 Q Okay. However, both of those were</p> <p>22 authored before you issued your first report in</p> <p>23 this litigation; correct?</p> <p>24 A Yes. I -- I added them as a -- when I</p>

<p style="text-align: right;">Page 34</p> <p>1 was looking at the request for materials to 2 provide, and I believe it requested any articles 3 that I had authored that touch on, or some such 4 phrasing, nitrosamines. And these two articles 5 do, and so it occurred to me that I should 6 provide them. I don't think I provided them 7 before. 8 MS. BOGDAN: 9 Okay. If we could take that down, 10 please. 11 Q Current employment? 12 A I'm sorry. Could you repeat that? It 13 cut off for a second. 14 Q What is your current employment? 15 A My current employment is a consultant 16 with Baertschi Consulting, LLC. 17 Q And how many employees does Baertschi 18 Consulting, LLC, have? 19 A One. 20 Q And how long have you been working for 21 Baertschi Consulting, LLC? 22 A Seven years, one month, and a week or 23 two. 24 Q And when you said there's one employee,</p>	<p style="text-align: right;">Page 36</p> <p>1 biotech, are you referring to pharmaceutical 2 companies that manufacture drugs? 3 A Some do. Some do not. Because some 4 are small companies or companies that have never 5 launched a product. So it -- if they haven't 6 launched a product, they're not a manufacturer. 7 A lot of companies I -- some of the 8 companies I consult with are virtual, and so 9 they're trying to bring a drug to market and 10 they're not a manufacturer themselves but they 11 contract it out. So there's a wide variety. 12 Some are -- do manufacture their own drugs. 13 Q And who are your clients that have 14 hired you for consulting purposes with regard to 15 nitrosamine impurities? 16 MR. HARKINS: 17 Object to the extent it calls for any 18 confidential information. 19 To the extent you're comfortable and 20 able to talk about that, you can answer. 21 A I can't provide you with the companies' 22 names, but I can say that because of the 23 confidentiality agreement I have with companies 24 is that I won't disclose their name without</p>
<p style="text-align: right;">Page 35</p> <p>1 I'm assuming that's you? 2 A Yes, ma'am. 3 Q Okay. Are you also a officer with the 4 LLC? 5 A I -- I don't think with an LLC we have 6 to designate officers, but if we do, I am. I -- 7 I think that was -- when I was looking to set it 8 up, I think that was a different type of 9 organization. 10 Q Are there any other principals in the 11 organization other than yourself? 12 A I do not believe so. 13 Q What is the business of Baertschi 14 Consulting, LLC? 15 A Providing consulting to any company 16 that would need but primarily to pharmaceutical 17 biotech, occasionally agrochemicals and 18 packaging, or sometimes instrumentation companies 19 related to my expertise, which is in impurities, 20 impurities identification, mutagenic impurities, 21 chemical drug degradation, formulation stability, 22 those sort -- photostability, photo safety, those 23 sorts of things. 24 Q And when you say to pharmaceutical</p>	<p style="text-align: right;">Page 37</p> <p>1 getting permission. But I -- there are a couple 2 of companies that I can't -- one company I can 3 disclose the name of. Well, I'd better not 4 because I'm not completely sure of that. 5 So I'm gonna say it's about four or 6 five companies that I have consulted with regard 7 to primarily risk assessments of nitrosamine 8 formation on stability. 9 MS. BOGDAN: 10 Q Have you been hired by any of the 11 defendants in this case to act as a consultant 12 with regard to nitrosamine impurities? 13 A No. 14 Can I ask a question? I've reviewed a 15 number of companies, and I think I've seen ten or 16 twelve and -- I don't know -- maybe even more 17 than that with some of the Rite Aid and CVS and 18 Walgreens. But I did not see any companies that 19 I have consulted with on the list, that I can 20 recall, with regard to nitrosamines. I'm pretty 21 sure of that. 22 Q Have you done work for any of the 23 companies in the past? 24 A On the broad list.</p>

<p style="text-align: right;">Page 38</p> <p>1 Have I done work for any companies on 2 the complete list of defendants? 3 Q Yes. 4 A I don't know that I know the complete 5 list of defendants. But, to my knowledge, the 6 ones I have looked at, I have not provided any 7 consulting to them. 8 Q Have you done any consulting work for 9 ZHP, Solco, or Prinston? 10 A No. 11 Q Have you done any consulting work for 12 Aurobindo, Mylan, or Teva? 13 A No. 14 Q Have you done any consulting work for 15 Torrent? 16 A No. 17 I'm starting to get uncomfortable in 18 that you could continue to list companies, and 19 then if you hit one that I have -- been a client 20 of mine, now I'm revealing that. So I'm starting 21 to get uncomfortable about whether or not you go 22 through a list of 20 or 30 companies and I -- 23 Because I've contracted with over 60 24 companies in the last 70 years -- seven years.</p>	<p style="text-align: right;">Page 40</p> <p>1 pharma companies? 2 A No. 3 Q What other type of companies do you do 4 work for? 5 A Agrochemical, animal health, and 6 instrument providers, instrumentation providers 7 that -- that make mass spectrometers or -- well, 8 mass spectrometers. 9 For example, I published a paper with 10 ACD/Labs. They're a software provider. So 11 the -- the article is a non-peer-reviewed 12 publication, so it's not privileged that I could 13 say that I worked with ACD/Labs. That's an 14 example of the kind of non-pharmaceutical 15 company. 16 Q What percentage of your business is 17 working for pharmaceutical companies? 18 A I don't have an accurate number from 19 calculating it, but I would estimate it at 90 20 percent. 21 Q And what is the other 10 percent? 22 A Other companies, non-pharmaceutical, or 23 litigation. 24 Q What percent of your work is</p>
<p style="text-align: right;">Page 39</p> <p>1 Q Well, part of serving as a consulting 2 expert in this litigation, I am absolutely 3 entitled to ask you if you have worked for any of 4 the defendants in the litigation in the past. 5 A Okay. If that's the legal standard, 6 then I'll answer any -- any questions. 7 MR. HARKINS: 8 Wait for a question. 9 MS. BOGDAN: 10 Q And, so, just so we can move on and 11 then we can maybe, you know, circle back to this, 12 with regard to the defendant list and the 13 documents you've reviewed, are there any of the 14 defendants that you know of as you sit here right 15 now that you have done work for in the past? 16 A No. 17 Q And when you say you've been hired by 18 60 companies in the past seven years, I'm 19 assuming you have a list of those 60 companies? 20 A I have -- I don't have a single list of 21 the companies, but I have records of all 22 consulting that I've done with companies. I mean 23 individual, not a combined list. 24 Q And are they all either biotech or</p>	<p style="text-align: right;">Page 41</p> <p>1 litigation-related? 2 A From -- in what time frame? Because 3 it's only been recently that I've had a few cases 4 in litigation. 5 Q Well, let's say in 2021. 6 A I would estimate 15 percent. 7 Q And the other non-pharmaceutical 8 companies that you do consulting work for, are 9 those companies somehow related to biotech or the 10 pharmaceutical industry? 11 A Related to -- 12 Q Meaning they provide instruments or 13 equipment that are used in biotech or the 14 pharmaceutical industry? 15 A Yes. They would be commercial vendors 16 that provide -- that sell instruments to not just 17 pharmaceuticals but the chemical industry, to 18 other related industries that use that kind of 19 advanced technology. 20 Q Like bioanalytical laboratories or that 21 kind of business? 22 A Exactly. Yes. 23 MS. BOGDAN: 24 If we could please pull up as an</p>

<p style="text-align: right;">Page 42</p> <p>1 exhibit the Baertschi Consulting, LLC, service 2 overview. It will be one of the last documents 3 loaded into the repository, if that's helpful. 4 (DEPOSITION EXHIBIT NUMBER 6 5 WAS MARKED FOR IDENTIFICATION.) 6 MS. BOGDAN: 7 Q Dr. Baertschi, can you see the exhibit? 8 A Yes. 9 Q And are we now on Exhibit 6 for 10 identification? 11 TRIAL TECH: 12 Correct. 13 MS. BOGDAN: 14 Q Do you recognize that exhibit? 15 A I do recognize it. 16 Q And under new expanded services, can 17 you read the section that begins "N-nitroso"? 18 A "N-nitroso/N-nitrosamine impurities and 19 risk assessments for the formulated product." 20 Q And what is involved with that type of 21 service? 22 A That type of service involves helping a 23 company do a risk assessment per the guidance 24 provided by EMA and maybe FDA as to what you</p>	<p style="text-align: right;">Page 44</p> <p>1 Eli Lilly. Is that my understanding? 2 A That is correct. 3 Q Okay. And your roles at Eli Lilly were 4 that of senior chemist and senior research 5 fellow? 6 A That's -- my starting position was 7 labeled as a senior chemist, and my ending 8 position was labeled -- the title is a senior 9 research fellow. 10 Q And what did your job responsibilities 11 entail in those positions with Eli Lilly? 12 A A wide -- it -- 13 Most of my responsibility focused on 14 helping assess stability, both predictive and 15 actual stability, and all the processes 16 associated with that. So that -- that has to do 17 with force degradation studies, also known as 18 stress testing studies, the degradation of drug 19 substances and drug products, the formulation and 20 how formulations might stabilize or 21 destabilize -- and that's both chemical and 22 physical stability -- and photo safety, 23 photostability studies and impurity isolation and 24 identification mechanistic understanding.</p>
<p style="text-align: right;">Page 43</p> <p>1 should do to carry out a risk assessment related 2 to the formation of nitrosamines as degradation 3 products, degradation-related impurities in the 4 formulated product. 5 So I don't -- I don't focus on 6 nitrosamine formation in synthetic routes or the 7 process impurity, the synthetic process as 8 process impurities. I focus on -- my -- my 9 expertise is on the potential formation 10 of N-nitroso compounds upon aging of a formulated 11 product. 12 Q When you say that your expertise is on 13 the potential formation of N-nitroso compounds 14 upon aging of a formulated product, you're 15 talking about nitrosamines forming as a result of 16 degradation? 17 A Yes. It would be classified as 18 degradation, yes. 19 Q Do you serve as a consultant with 20 regard to doing a risk assessment of the 21 synthetic process that is used to manufacture the 22 drug? 23 A I have not. 24 Q Now, you previously worked for</p>	<p style="text-align: right;">Page 45</p> <p>1 And I also, by the time I was done, was 2 mentoring a wide variety of other scientists, 3 and -- and part of my responsibilities were to 4 mentor the next generation of scientists. 5 Q So, from that response, I gather that 6 your work at Eli Lilly also pertained to studying 7 degradation of drug substances and products and 8 studying what can happen to them after they're 9 produced but before they would be taken by the 10 patient? 11 MR. HARKINS: 12 Object to form. Compound. Vague. 13 You can answer. 14 A Yes. I would agree with that 15 statement, that I -- the statement is that I 16 would -- my expertise focused on helping 17 understand what degradation products could and do 18 form prior to the exposure to the patient. 19 MS. BOGDAN: 20 Q Would an analysis of the chemical 21 synthesis route that was used to create the drug 22 be important to understand as an initial matter 23 when looking at potential degradation pathways? 24 MR. HARKINS:</p>

<p style="text-align: right;">Page 46</p> <p>1 Object to form. Speculation. Vague.</p> <p>2 A Looking at the synthetic route and</p> <p>3 understanding the potential impurities and the</p> <p>4 chemistry associated with forming the drug</p> <p>5 substance can be of use in some circumstances</p> <p>6 because sometimes the molecule can fall apart in</p> <p>7 a same -- one step or two in the same manner it</p> <p>8 was put together. Sometimes that's not possible.</p> <p>9 But the process impurities that result</p> <p>10 from that are oftentimes used as a starting point</p> <p>11 for the analytical method development to -- to</p> <p>12 generate a stability-indicating method. So you</p> <p>13 have the -- the process impurities method as a</p> <p>14 starting point, and then you need to develop a</p> <p>15 stability-indicating analytical method, which</p> <p>16 means it would detect any and all degradation</p> <p>17 products that might form and do form.</p> <p>18 MS. BOGDAN:</p> <p>19 Q So understanding that process</p> <p>20 impurities method would be part of what you did</p> <p>21 when you were looking at potential degradation</p> <p>22 products in your role at Eli Lilly?</p> <p>23 A As a starting point, we would look at</p> <p>24 the process impurities and the methods that had</p>	<p style="text-align: right;">Page 48</p> <p>1 forced degradation studies, also known as stress</p> <p>2 testing studies, to process impurity discovery,</p> <p>3 structure elucidation and mechanistic chemistry,</p> <p>4 and to analytical method development.</p> <p>5 Q Okay. So when you refer to design and</p> <p>6 development of analytical methods, what do you</p> <p>7 mean by analytical method?</p> <p>8 A I mean a method that will enable the</p> <p>9 separation of the -- the parent drug from any</p> <p>10 associated impurities and a detection of the</p> <p>11 other impurities with some form of quantitation,</p> <p>12 quantification.</p> <p>13 Q So that would be assisting as -- with</p> <p>14 developing the appropriate test in order to</p> <p>15 identify an impurity and then be able to quantify</p> <p>16 it?</p> <p>17 A Yes.</p> <p>18 Q And depending on what impurity is in a</p> <p>19 drug, that governs what test is appropriate to</p> <p>20 detect it and then quantify it; correct?</p> <p>21 A Um, could you repeat that question?</p> <p>22 Q And I can -- I can rephrase it for you.</p> <p>23 When determining what test is</p> <p>24 appropriate to detect an impurity and quantify</p>
<p style="text-align: right;">Page 47</p> <p>1 been developed to date as the starting point for</p> <p>2 analytical method development for stability. So</p> <p>3 I'm -- I believe I'm agreeing with your</p> <p>4 statement.</p> <p>5 MS. BOGDAN:</p> <p>6 If you could please pull back up</p> <p>7 Exhibit 6. If we could go to the second page.</p> <p>8 Q Doctor, do you see the box that is</p> <p>9 entitled "analytical and mutagenic impurity</p> <p>10 control strategies"?</p> <p>11 A I do see that box.</p> <p>12 Q Okay. And what services are you</p> <p>13 advertising that are available through your</p> <p>14 company with regard to that...</p> <p>15 A Did you finish your question?</p> <p>16 Q With regard to that -- with regard to</p> <p>17 analytical mutagenic impurity control strategies?</p> <p>18 A I'm advertising that -- that I can</p> <p>19 assist with or provide consulting related to the</p> <p>20 design and development of analytical methods for</p> <p>21 ordinary impurities as well as for mutagenic</p> <p>22 impurities, that I can provide services related</p> <p>23 to troubleshooting of analytical methods, to</p> <p>24 solving analytical artifact issues, to leveraging</p>	<p style="text-align: right;">Page 49</p> <p>1 it, it is important to know what the impurity is;</p> <p>2 correct?</p> <p>3 A Yes. You -- you -- it's not always</p> <p>4 universally that situation, but, in general, yes.</p> <p>5 Q You help develop analytical methods and</p> <p>6 tasks in order to find and quantify impurities;</p> <p>7 correct?</p> <p>8 A Yes.</p> <p>9 Q Now, you mentioned two different types</p> <p>10 of impurities. You mentioned ordinary</p> <p>11 impurities. Can you please describe what you</p> <p>12 mean by ordinary impurities?</p> <p>13 A Traditionally -- historically, I should</p> <p>14 say, that is a term coined by USP to describe</p> <p>15 related substances. Ordinary impurities might be</p> <p>16 anything that is related to the synthesis or the</p> <p>17 degradation of a drug substance, and the ordinary</p> <p>18 part of it implies that it's not particularly</p> <p>19 toxic.</p> <p>20 Q Then you have another category of</p> <p>21 genotoxic mutagenic impurities. What do you mean</p> <p>22 by that?</p> <p>23 A There -- the -- the terminology</p> <p>24 there -- mutagenic is a subset of genotoxic</p>

<p style="text-align: right;">Page 50</p> <p>1 impurities, and mutagenic impurities are the 2 subset of potentially toxic impurities that have 3 been identified by ICH M7, a particular guidance 4 document to characterize molecules that might 5 react with DNA. 6 And, so, they have the potential for 7 reacting with DNA and causing a mutation. 8 Q And why did you bullet-point these two 9 types of impurities as opposed to just saying 10 impurities as one category? 11 A Because the challenges associated with 12 detecting and quantifying mutagenic impurities 13 are somewhat -- they're somewhat unique, more 14 difficult because of the low levels for -- when 15 you have identified a mutagenic or genotoxic 16 impurity for controlling or -- or measuring. 17 So it's -- you don't typically apply 18 the same analytical techniques because you need 19 more sensitivity. And -- 20 Q Why are -- 21 I'm sorry. 22 A And there's certain expertise in -- in 23 that process of assessing and doing a mutagenic 24 risk assessment and trying to carry through that</p>	<p style="text-align: right;">Page 52</p> <p>1 MR. HARKINS: 2 Object to form. Scope. Vague. 3 A Yeah. I'm struggling with that 4 question, why is it important. I feel like I 5 just answered why it's important, but maybe I 6 spoke too technically. 7 MS. BOGDAN: 8 Q Why are genotoxic and mutagenic 9 impurities a concern? 10 MR. HARKINS: 11 Same objection. 12 A They're a concern because a mutagen has 13 potential and it has to do with whether or not 14 it's -- 15 I won't go too far, but if you want to 16 go to talk about this further, we can. It's 17 because mutagens can react potentially with DNA. 18 And if a mutagen reacts with DNA and it's 19 ingested by an animal or a person, it can then 20 react with DNA. Reactions with DNA can be the 21 initiating start of -- of cancer. 22 MS. BOGDAN: 23 Q The next service that you indicate in 24 that part of your website is troubleshooting</p>
<p style="text-align: right;">Page 51</p> <p>1 process as outlined by ICH M7. 2 Q Why are genotoxic and mutagenic 3 impurities controlled at low levels? 4 A Well, I'm struggling with the word 5 "controlled at low levels." The thresholds for 6 when you need to -- where -- the thresholds for 7 controlling them are much lower than the 8 thresholds for controlling ordinary impurities, 9 and that's because they're much more potentially 10 toxic. 11 Q And why are they much more potentially 12 toxic? 13 MR. HARKINS: 14 Object to form. Scope. 15 A They're much more potentially toxic 16 because they specifically react or they can 17 specifically react with DNA to form a mutation. 18 So that's different from the general 19 concern of toxicity, which would not be 20 associated with DNA reaction. 21 MS. BOGDAN: 22 Q And why is it significant that 23 genotoxic and mutagenic impurities can react with 24 DNA to form mutations?</p>	<p style="text-align: right;">Page 53</p> <p>1 analytical methods. What do you mean by that? 2 A I mean sometimes companies will have an 3 analytical method, and then they're -- they start 4 to see -- have problems with it, like all of us. 5 They might be having a problem with variation of 6 peak size or with peaks moving in a relative 7 retention or with anomalous peaks that show up, 8 artifactual peaks, or with a method that they're 9 unsure -- they can't seem to figure out how to 10 sharpen up a peak because it's broad, it's 11 double-peaked, things like that. 12 And, so, you -- you -- I can provide 13 help in doing chromatographic troubleshooting to 14 sharpen up the peaks, to elude all the peaks. 15 You know, there are ways to tweak an analytical 16 method to make it perform better. 17 Q I was gonna ask you -- you started to 18 talk about peaks. And what are peaks, the peaks 19 that you're referring to? Are you talking about 20 peaks on chromatograms or some other type of 21 test? 22 A I am talking about peaks in a 23 chromatogram. So that's kind of jargon for those 24 in the field. The way you separate impurities</p>

<p style="text-align: right;">Page 54</p> <p>1 is -- one example of a way you separate 2 impurities by HPLC is where the solution is 3 injected into a column, it goes through the 4 column at a certain rate because the solvent 5 pushes it along, and different compounds migrate 6 through that column at different rates. 7 And when they come out of the column, 8 they're detected by a detector, they're sensed by 9 a detector, and that detector gives a response 10 per the amount there or per some feature of that 11 molecule, and it will give a time-based 12 chromatogram where the peaks are associated with 13 some kind of impurity or non- -- process related, 14 degradation related, or extraneous leachable type 15 of material. 16 Q And, so, you provide services reviewing 17 analytical methods, and specifically 18 chromatograms, in an effort to help refine the 19 process and make those testing methods better? 20 A That would not comprehens- -- not 21 comprehensibly describe it, but that is 22 certainly -- I agree with the way you 23 characterized it. 24 Q And is this limited to HPLC or does it</p>	<p style="text-align: right;">Page 56</p> <p>1 extensive. And, again, I have a lot of tips and 2 tricks and things that I've learned along the 3 way. So depending on how you define expert, you 4 might consider -- I might hold myself out as an 5 expert. 6 But I just know of people who work -- 7 have worked for 20, 30, 40 years exclusively on 8 mass -- on mass spectrometry, and they have more 9 expertise than me. So on a relative basis, I 10 wouldn't hold myself as that kind of an expert. 11 A user functional expert, I have -- I have -- I 12 am comfortable with that topic. 13 MS. BOGDAN: 14 Q But you would refer [sic] to those 15 people that have 20, 30, or 40 years of work with 16 mass spectrometry if there was an issue with 17 regard to troubleshooting a mass spectrometry 18 analytical method? 19 A It seems like that question was 20 incomplete. You said I would refer to these 21 people -- 22 Q You would defer. I'm sorry. 23 A Defer. Defer. I -- I would engage 24 and -- yes. I think defer means that if we had</p>
<p style="text-align: right;">Page 55</p> <p>1 also involve chromatograms from other types of 2 analytical testing? 3 A Primarily focused on HPLC, but I have 4 expertise beyond HPLC. So it could involve other 5 type of separation methods and techniques. 6 Q And what other type of separation 7 methods and techniques are you referring to? 8 A The -- the most obvious one, the first 9 one would be gas chromatography. 10 Q Do you also consult with regard to mass 11 spectrometry? 12 A Yes. But I no longer can hold myself 13 out as a mass spectrometry expert. I consider 14 myself well versed in mass spectrometry, and, 15 yes, I can help in those issues. But I -- it's 16 not a typical consulting topic that I am -- am 17 asked about. 18 Q So you consider yourself an expert with 19 regard to HPLC and GC but not MS? 20 MR. HARKINS: 21 Object to form. Misstates testimony. 22 You can answer. 23 A I believe that my expertise in mass 24 spectrometry is pretty broad and pretty</p>	<p style="text-align: right;">Page 57</p> <p>1 a -- 2 Generally, those kind of people are 3 gonna have more insight into troubleshooting than 4 I would. 5 Q And, just so the record is clear, I 6 started to use some acronyms there, and I'm sure 7 we're gonna use them going forward, but let me 8 ask you for the record. When you say HPLC, what 9 are you referring to? 10 A High performance liquid chromatography. 11 Q And when you say GC, what are you 12 referring to? 13 A Gas chromatography. 14 Q And when you say MS, what are you 15 referring to? 16 A Mass spectrometry. 17 Q Now, the next service that you 18 advertise is solving analytical artifact issues. 19 What is meant by that description of the service 20 that you provide? 21 A It -- in general, artifacts have to do 22 with peaks that show up that sometimes are 23 spurious, sometimes are variable. Sometimes 24 they're not spurious or variable, but they're not</p>

<p style="text-align: right;">Page 58</p> <p>1 associated with anything to do with what was in 2 the solution that you're analyzing but are a 3 phenomenon of something else, such as on-column 4 degradation. So if a -- or on-column reaction. 5 So as a compound proceeds through the 6 separation column, sometimes it can do reactions 7 with things in the column, with trace metals, 8 with other things, and can produce an artifactual 9 impurity that's not part of the original 10 solution, so it's an artifact from the analytical 11 preparation workup or separation or analysis. 12 Q You used a couple different terms in 13 that response. One was "spurious." Can you 14 please define what you mean by that term, 15 "spurious"? Spurious? 16 A Unpredictably showing up. It occurs 17 occasionally in an unpredictable way. 18 Q And then you also referred to artifacts 19 as being variable. What did you mean by the term 20 "variable"? And how does that differ from 21 spurious? 22 A Variable would, to me -- I was implying 23 that maybe an artifact peak might go up and down 24 in size, might sometimes split into two peaks and</p>	<p style="text-align: right;">Page 60</p> <p>1 what's the source of the artifact, and because I 2 have worked for a long time in that area and 3 published on it, it's -- it's fairly frequent 4 that I have experienced that particular type of 5 artifact that they're seeing and can troubleshoot 6 it by providing them with, okay, try this change 7 and see what happens to the peak, add this to the 8 mobile phase of the -- of the system and see how 9 that affects the peak shape or eliminates it. 10 So there are some commonalities and 11 repeated motifs that happen with artifacts, and 12 I'm familiar with, you know, more than a dozen of 13 those kinds of issues and how to track it down 14 and identify the root cause and solve it. 15 Q Is it prudent for a company, if they're 16 having artifact issues, to do an analysis to 17 determine the cause of those artifacts that 18 they're seeing when using chromatography? 19 MR. HARKINS: 20 Object to form. Vague. Scope. 21 A So I'm hearing the question as is it 22 prudent for a company to investigate and -- and 23 try to understand or solve artifact peak problems 24 that they are seeing. I would say it is prudent</p>
<p style="text-align: right;">Page 59</p> <p>1 sometimes not. So spurious would mean it shows 2 up in your chromatogram unexpectedly sometimes, 3 and you don't know why at the start. 4 And, to me, the -- I use the term 5 "variable" means it's showing up regularly but 6 it's varying in how it appears in the 7 chromatogram in either level or shape. 8 Q Is it showing up at the same retention 9 time if you're using the term "variable"? 10 A You know, that's an imprecise term. 11 There's no clear definition. So it -- 12 Variable could -- could involve moving 13 a retention time as well. I'm not trying to be 14 restrictive. I'm trying to emphasize that there 15 is a variation, and sometimes it's predictable -- 16 or sometimes it's more -- when it -- when you 17 don't see one and you see a peak versus the peak 18 shows up somewhat regular -- pretty regularly but 19 it varies in appearance or retention time or 20 shape. 21 Q And what services do you provide in 22 order to help solve these spurious or variable 23 peaks with regard to chromatogram? 24 A I help companies figure out first</p>	<p style="text-align: right;">Page 61</p> <p>1 for that to occur. It may not always be 2 necessary, depending on the type of artifact 3 occurring, but it's -- it's prudent to be able to 4 investigate, understand the issue, because -- 5 because it can affect your analytical results. 6 MS. BOGDAN: 7 Q And you actually are hired by companies 8 to investigate and understand artifact peaks that 9 they are seeing in chromatograms; correct? 10 A Yes. But when -- just to make sure you 11 understand what "hired" means, doesn't mean I 12 conduct any laboratory work, because I have no 13 laboratory. I am only providing intellectual 14 input. So I come up with ideas, suggestions, 15 experiments. I can help them, as they carry them 16 out, interpret the results and point them to the 17 underlying chemistry issue, as my background in 18 organic chemistry, my Ph.D. provide me -- and 19 experience provide me with that chemistry 20 background that oftentimes helps solve and 21 uncover the root cause of these kinds of artifact 22 issues. 23 Q Using the term "root cause," can you 24 describe what you mean by that?</p>

<p style="text-align: right;">Page 62</p> <p>1 A Yeah. Another term could be "trigger," 2 but I think root cause is a better term. Root -- 3 the root cause might be what's the underlying 4 phenomenon that -- that is the source of whatever 5 problem you're dealing with. 6 So if you're having an artifact 7 associated with a particular root cause, if you 8 can say, oh, it is because you're operating at a 9 high pH, your mobile phase is at a high pH and 10 you're using a metal frit and that metal is 11 ablating off the frit and it's depositing on the 12 head of the column and, as the compound passed 13 by, that transition -- one of the transition 14 metals is catalyzing on column degradation, so 15 that's an example of if you understand the root 16 cause, then you can say, oh, we can solve that by 17 replacing with a plastic frit, or we can change 18 the pH of the HPLC separation so that it no 19 longer ablates metal off the metal frit. 20 So I'm not trying -- I'm just trying to 21 give one example of how that plays out, the root 22 cause investigation. 23 Q I appreciate that. 24 So it's important to determine what the</p>	<p style="text-align: right;">Page 64</p> <p>1 understanding as long as you know that your 2 control is robust. 3 MS. BOGDAN: 4 Q The next service that you mentioned is 5 leveraging forced degradation studies. Would 6 that pertain to stress testing, for example? 7 A Yes, it would. Forced degradation and 8 stress testing are sometimes used colloquially as 9 jargon as the same term. 10 Q The next service that you advertise is 11 process impurity discovery, structure 12 elucidation, and mechanistic chemistry. What 13 services is that bullet point describing? 14 A That's describing -- it's analogous to 15 if you're looking at -- at new peaks on a 16 stability sample that come up that you know 17 are -- are degradation-related in your synthetic 18 process if you have peaks beside your -- your API 19 or beside your intended step product that 20 elute -- you -- you can -- it can be helpful to 21 determine the structure of those impurities that 22 occur during the process, during the synthetic 23 process and, therefore, called process 24 impurities. It can be useful to --</p>
<p style="text-align: right;">Page 63</p> <p>1 underlying phenomenon is that's causing a peak in 2 a chromatogram? 3 MR. HARKINS: 4 Object to form. Scope. Vague. 5 A Yeah. We were talk- -- we're in the 6 context of artifact issues, and it would relate 7 to the size of the peak. So if a peak is an 8 artifact but it doesn't affect the quantitation, 9 like it's so small that it doesn't affect, you 10 can ignore things that are very small. 11 So there are examples when you wouldn't 12 need to solve or prevent or understand a root 13 cause, and there's often times when there's 14 unknowns at levels where you don't need to 15 investigate. 16 But for -- for things that are 17 affecting your analytical results or changing how 18 you would process the integration of a sample, 19 yeah, those artifact issues would be important to 20 under- -- to understand and control -- understand 21 at least to the point of control. The 22 understanding that you need is guided by the -- 23 the desire to control it. So you can sometimes 24 control things without having a full root cause</p>	<p style="text-align: right;">Page 65</p> <p>1 You don't always have to do those. It 2 depends on the levels and the amounts and whether 3 or not there's mechanistic help, like if you're 4 getting low yields and you're trying to 5 understand how to increase your yields. But 6 that's how I would frame it. 7 Q Okay. And when you say "process 8 impurity discovery," that would be impurities 9 that are created by the synthetic process itself; 10 correct? 11 A Yes. 12 Q And when you say "structure 13 elucidation," what are you referring to? 14 A I'm referring to determining the 15 molecular structure of the impurity itself. 16 Q When you say "the molecular structure," 17 is that actually identifying what the impurity 18 is? 19 A Yeah. It doesn't identify -- 20 Yes. It identifies what it is at a -- 21 at a fairly fundamental level, what the -- how 22 the atoms are arranged together in space that 23 comprise that compound. 24 Q And why would you want to know that</p>

<p style="text-align: right;">Page 66</p> <p>1 information?</p> <p>2 A Um, because if you understand the</p> <p>3 structure of an impurity, it can help you</p> <p>4 postulate or figure out how it's forming. And</p> <p>5 sometimes that information can be useful in</p> <p>6 tweaking or changing the synthetic step to avoid</p> <p>7 the impurity, to decrease in an area and to</p> <p>8 increase the yield of the desired intermediate or</p> <p>9 API that you're synthesizing.</p> <p>10 Q And how do you determine the molecular</p> <p>11 structure of the impurity?</p> <p>12 A Usually that would involve a</p> <p>13 combination of mass spectrometry, and there's</p> <p>14 various ways -- there's high resolution. There's</p> <p>15 fragmentation studies. So you use the general</p> <p>16 technique of mass spectrometry coupled with NMR,</p> <p>17 nuclear magnetic resonance, to definitively prove</p> <p>18 a structure.</p> <p>19 Q And those are analytical tests that are</p> <p>20 typically used in the pharmaceutical industry to</p> <p>21 determine what a structure is; correct?</p> <p>22 A I would not say they are analytical</p> <p>23 tests. I would say they are spectroscopic</p> <p>24 techniques that are used to elu- -- to determine</p>	<p style="text-align: right;">Page 68</p> <p>1 I'm trying not to get into, like, a</p> <p>2 professorial mode and start talking chemistry and</p> <p>3 losing everyone more than I already do, because,</p> <p>4 as my wife tells me, it can be pretty boring.</p> <p>5 MR. HARKINS:</p> <p>6 You're doing just fine.</p> <p>7 MS. BOGDAN:</p> <p>8 Q I am following you, so...</p> <p>9 And when you're talking about the</p> <p>10 mechanistic chemistry, again, you're talking</p> <p>11 about an analysis of the chemical synthesis</p> <p>12 process that is used to make the drug?</p> <p>13 A It's -- it's almost like a subset of an</p> <p>14 analysis of the chemical synthesis. It's -- it's</p> <p>15 more like how does this molecule get formed</p> <p>16 with -- under what conditions with -- with what</p> <p>17 precursors? What is attacking what? What is</p> <p>18 leaving what?</p> <p>19 And, so, it's -- it's kind of like</p> <p>20 the -- the detailed -- the nauseating details of</p> <p>21 the chemical reaction that's occurring.</p> <p>22 Sometimes that mechanistic insight is very useful</p> <p>23 for control strategies or for ways to avoid or</p> <p>24 maximize the formation of something, and</p>
<p style="text-align: right;">Page 67</p> <p>1 the structure of compounds.</p> <p>2 Q Those are spectroscopic techniques that</p> <p>3 are typically used in the pharmaceutical industry</p> <p>4 to determine the identity of a structure?</p> <p>5 A I missed the very first part. You cut</p> <p>6 out. Can you repeat the question?</p> <p>7 Q So mass spectrometry and NMR are</p> <p>8 spectroscopic techniques that are typically used</p> <p>9 in the pharmaceutical industry to determine the</p> <p>10 identity of a structure?</p> <p>11 A Yes, I would agree with that.</p> <p>12 Q Now, you specifically mention</p> <p>13 mechanistic chemistry. How does mechanistic</p> <p>14 chemistry relate to process impurity discovery</p> <p>15 and structure elucidation?</p> <p>16 A I -- I would say mechanistic chemistry</p> <p>17 is kind of a fancy way of saying understanding</p> <p>18 the root cause in a chemistry environment. So</p> <p>19 mechanistic would involve understanding the</p> <p>20 chemistry. I -- I think, in a general sense, it</p> <p>21 helps you identify the -- the sort of way some --</p> <p>22 the process by which something is formed at a</p> <p>23 molecular level such that it gives you insight</p> <p>24 into the root cause.</p>	<p style="text-align: right;">Page 69</p> <p>1 sometimes the mechanistic insight gives you no</p> <p>2 handles to play with, to -- to optimize or</p> <p>3 divert.</p> <p>4 So it's kind of like your son coming</p> <p>5 home and he has a black eye and you're trying to</p> <p>6 figure out what was the mechanism. Okay. A kid</p> <p>7 punched him, but was he falling into him because</p> <p>8 he tripped over a rock?</p> <p>9 And so you're looking at the specifics</p> <p>10 of how the chemistry -- how the two molecules</p> <p>11 came together to form a reaction, and it's --</p> <p>12 it -- it's a form of root cause investigation,</p> <p>13 you could say.</p> <p>14 Q And that's actually sort of a</p> <p>15 theoretical assessment; right? It's done on</p> <p>16 paper?</p> <p>17 A It's done on paper, but the -- it can</p> <p>18 be tested. So based on the mechanistic insight</p> <p>19 that you get, you can test the mechanism by</p> <p>20 saying if this is the mechanism, then if we</p> <p>21 change this, something different will happen.</p> <p>22 Then you can do experiments to change</p> <p>23 conditions and tests to prove your mechanism</p> <p>24 further, because mechanisms can never be</p>

<p>Page 70</p> <p>1 unequivocally proven, but they can be a consent 2 upon or they can be pretty strong such that 3 they're -- they would be agreed upon and useful 4 for manipulating the reactions. 5 Q So you would develop a theory of the 6 mechanistic chemistry but then design testing to 7 see if the theory is correct? 8 A Yes. I would say that is -- you can do 9 that. You don't have to do that when you come up 10 with the mechanism. But, yes, that's what a 11 mechanism would enable you to do. And sometimes 12 the mechanism doesn't enable you to test it very 13 well because it can be very complex. 14 But some mechanism -- many mechanisms 15 are amenable to design of new tests to help 16 understand further and further control or modify. 17 Q And the last service that you advertise 18 in that section is analytical method development. 19 What is meant by that? 20 A It's -- it's kind of like what happens 21 before you're troubleshooting an analytical 22 method. So if you have a -- if you need to 23 separate and detect all of the -- the degradation 24 products that occur for a product on stability,</p>	<p>Page 72</p> <p>1 can carry it out? How linear is the response 2 to -- of the detector to differences in levels of 3 impurities or the API of the drug substance 4 itself? 5 So it's -- it's sort of confirming that 6 the method can perform up to the -- up to the 7 needs that are -- are required to ensure that the 8 method performs well. 9 Q So is testing the analytical method 10 used to determine if the testing method is 11 accurate? 12 A Yeah. There's an accuracy component 13 of -- of the method. There -- yes. There's an 14 accuracy component to it. 15 MS. BOGDAN: 16 We can take that exhibit down. 17 MR. HARKINS: 18 Hey, Rosemarie, if you're moving on to 19 something else, we've been going for about an 20 hour and a half. I just wanted to check if the 21 doctor needs a break. 22 THE WITNESS: 23 Yeah, that would probably be a good 24 idea to take a short break.</p>
<p>Page 71</p> <p>1 you -- you -- you need to be able to anticipate 2 what would happen in two, three, sometimes five 3 years, and you can't wait five years for that to 4 happen, so you have to figure out how do we come 5 up with those compounds and how do we -- how do 6 we provide an analytical method that's likely to 7 detect the compounds based on what we can do in a 8 shorter time? 9 So it's -- it's, from the ground up, 10 what method, what separation method should we 11 use, what -- and -- and then how do we put meat 12 on the bones? How do we, you know, make certain 13 choices that we can with an analytical method 14 that's most likely to succeed, and then how do we 15 test it and continue to develop it until it's 16 comprehensive and accurate? 17 Q Why is testing the analytical method 18 important? 19 A To make sure you understand if it's 20 robust, if you can transfer it from one lab to 21 another. If -- if you're doing a method every 22 day, how does it vary day to day? How does it 23 vary as a function of the person carrying it out? 24 How well is it described so that different people</p>	<p>Page 73</p> <p>1 MR. HARKINS: 2 Want to say five minutes? 3 MS. BOGDAN: 4 Just five minutes? If we could limit 5 the break to five minutes, that would be good. 6 MR. HARKINS: 7 Would that be good for you, Doctor? 8 THE WITNESS: 9 Yes. Can we make it six? Can we make 10 it seven? 11 MS. BOGDAN: 12 Yes, we can make it seven. I don't 13 know how long the walk is for you. Because 14 lawyers tend to like to take lots and lots of 15 breaks, so I'm trying to -- 16 THE WITNESS: 17 I'm not a lawyer. 18 MS. BOGDAN: 19 I know. I like to avoid taking so many 20 breaks that we end up having the deposition go 21 three more hours than it needs to. That's all. 22 But certainly if you as the witness 23 needs a break at any time, please let me know. 24 And we always can accommodate everybody, so --</p>

<p>Page 74</p> <p>1 THE WITNESS: 2 Okay. Great. 3 MR. HARKINS: 4 Can we go off the record? 5 VIDEOGRAPHER: 6 Off record, 10:40 a.m. 7 (OFF THE RECORD.) 8 VIDEOGRAPHER: 9 On record, 10:48 a.m. 10 MS. BOGDAN: 11 Okay. If we could please pull up the 12 doctor's invoices. 13 (DEPOSITION EXHIBIT NUMBER 7 14 WAS MARKED FOR IDENTIFICATION.) 15 MS. BOGDAN: 16 Q Now, my first question, Dr. Baertschi, 17 is did you have a separate retainer agreement 18 with Greenberg Traurig? 19 A No. 20 Q There is no -- there is no retainer 21 agreement? 22 A Correct. 23 MS. BOGDAN: 24 Now, is this marked as Exhibit 7?</p> <p>Page 75</p> <p>1 Where are we with exhibits? 2 MR. HARKINS: 3 I think it's 7. 4 MS. BOGDAN: 5 Q Take a look at this exhibit and tell me 6 if these are your complete invoices for the work 7 that you've done on this matter. 8 A Yes, they are. It is a little 9 embarrassing when I make invoices to think that 10 it's going to be displayed to a bunch of people. 11 I'm not that diligent in how I record my time. 12 But, anyway, you can see what I did. 13 Q And when you say you're not that 14 diligent in how you record your time, what do you 15 mean by that? 16 A I mean the -- the line describing what 17 I did isn't always comprehensive, and sometimes 18 it's -- it's too -- sometimes it's too detailed. 19 But it's just helping me document that I was 20 doing something and how long I did it. The 21 amount of time is accurate. 22 Q Okay. 23 A It's a general note to say this is the 24 kind of stuff I was doing in that time period.</p>	<p>Page 76</p> <p>1 Q So for these invoices, when I total 2 them all up, it looks like you did about 77 hours 3 of work on this case through the time -- through 4 the date of your last invoice. 5 A Okay. 6 Q Does that sound about right to you? 7 A That -- yeah. I haven't done the math, 8 but that sounds reasonable, yes. 9 Q And that was the -- through the invoice 10 that you served January 3rd of 2022, which is the 11 last invoice in this series in Exhibit 7. 12 A Okay. 13 Q How many hours have you spent on this 14 matter since your last invoice? 15 A I don't know off the top of my head, 16 but let me see if I can kind of come up with a 17 rough ballpark-ish. 40? 30? I -- I'm... 18 Q Thirty to 40 more hours? 19 A Well, I don't want to say that it's 20 definitely in that range. 21 Q Okay. 22 A But 50, in that kind of range, that's a 23 ballpark-ish range that sounds right to me. 24 Q When you have in your invoices the</p> <p>Page 77</p> <p>1 letters ER, is that referring to expert report? 2 A Yes. 3 Q And then you have a reference on 4 December 29th, 2021, to work on getting UV 5 information for NDMA and for valsartan related to 6 relative response factor. 7 A Yes. 8 Q Can you describe what UV information is 9 for NDMA? 10 A I was trying to understand if -- if 11 NDMA absorbed radiation in the wavelength range 12 where the method -- the analytical method for 13 impurities was centering on, which is, I believe, 14 if I recollect correctly, 230 nanometers. 15 So I was looking for information on the 16 UV spectrum of NDMA and valsartan and looking at 17 how much absorbance occurs out in that region. 18 Q What did you learn from your 19 investigation? 20 A I did not get definitive information, 21 but I was -- what I -- what I got was enough to 22 know that NDMA does appear to have some 23 absorbance out in the 230 nanometer region, if I 24 remember correctly, but it would likely be --</p>
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<p style="text-align: right;">Page 78</p> <p>1 have a lower response factor than valsartan. 2 So it would -- which means if -- if you 3 had a .1 percent peak of -- 4 It means you have less sensitivity to 5 be able to detect NDMA using a UV detector. It 6 would be more difficult than the same amount of 7 valsartan. 8 Q When you say -- 9 A This also -- 10 Q I'm sorry. 11 A This also potentially relates to 12 something I saw in the Najafi deposition where he 13 said that nitrosamines have no absorbance in the 14 UV and you wouldn't detect them at all in a UV, 15 in a UV detector. And I don't agree with that. 16 Q So you found that NDMA does have some 17 absorbance in the 230 nanometer region? 18 A That's what I recollect. The reason -- 19 and I'm a little leery of saying definitively 20 because that absorbance is dependent on the 21 solvent. And I -- I was looking for general 22 information to see if it was really worth 23 exploring, and I kind of, after looking for a 24 while, I decided it wasn't really worth</p>	<p style="text-align: right;">Page 80</p> <p>1 Q Did you do any type of testing of NDMA 2 or ask for testing to be done of NDMA to see if 3 it had absorbance at 230 nanometers? 4 A No, I did not. 5 Q So you didn't do anything independently 6 to verify this one way or the other? 7 A Correct. 8 Q What reference source were you 9 consulting with regard to whether NDMA has 10 absorbance at 230 nanometers? 11 A I believe I was doing searches on 12 either Google Scholar or SciFinder, looking for 13 NDMA, NDEA, and other related compounds, small 14 N-nitroso compounds, and UV response, UV 15 spectrums, a variety of terms like that, and then 16 looking at the abstracts of papers and deducing 17 what I could, to the best of my recollection. 18 Q Did any of these resources that you 19 found and read make it into your references for 20 this report? 21 A I don't think so, because I don't think 22 I commented on NDMA relative response factor in 23 my expert report. 24 Q Did any of these resources make it into</p>
<p style="text-align: right;">Page 79</p> <p>1 continuing to explore because I didn't think it 2 was a -- a -- a big factor. 3 So, for example, if NDMA had a really 4 huge response, then -- at 230 nanometers, then 5 you might be able to detect very low levels of it 6 with a method at 230 nanometers. But I didn't 7 find that, so I kind of abandoned that 8 investigational route. And I don't exactly 9 remember such that I'm willing to say in a 10 deposition under oath that it does not have or it 11 does have absorbance at 230. That's to the best 12 of my recollection. 13 Q So you did not get definitive 14 information on whether NDMA has absorbance at the 15 230 nanometer region that would allow you to give 16 an opinion in this regard? 17 A I would say I would need to review that 18 in order to -- 19 I -- I can't recall confidently, 20 definitively here as I sit. I -- I don't -- so I 21 would have to refresh my memory to make sure. 22 But I believe my best recollection is, more 23 likely than not, yes, it does have some 24 absorbance at 230 nanometer.</p>	<p style="text-align: right;">Page 81</p> <p>1 your materials considered list? 2 A I don't think so, because I don't think 3 I actually downloaded articles and digested them 4 thoroughly and verified the -- the pictures that 5 I was seeing. 6 Q As you sit here today, can you say with 7 a reasonable degree of scientific certainty 8 whether NDMA has absorbance at 230 nanometers? 9 A No. 10 Q As you sit here today, can you say with 11 a reasonable degree of scientific certainty 12 whether NDMA will appear on an HPLC test? 13 A That's an incomplete sort of question, 14 but I think you mean will an HPLC tested with UV 15 protection presumably at the wavelength that 16 they're using in the compendial methods, which I 17 believe is 230 nanometers. 18 I cannot say for sure that if you had a 19 high enough level of NDMA that you would detect 20 it at that wavelength. I concluded tentatively 21 in my research that it would, but I didn't 22 actually do enough work to -- to make -- to nail 23 that down, as you said, so where I could sit here 24 today and stand by that or sit by it.</p>

<p style="text-align: right;">Page 82</p> <p>1 Q And when you're talking about the 2 compendial standard, are you talking about the 3 USP monograph or are you referring to some other 4 standard? 5 A Yes. I would be referring to the USP 6 monographs and/or the analytical methods that I 7 reviewed that were being used, for example, by 8 Teva for impurities in valsartan. 9 Q And was Teva using the impurity method 10 that is set forth in the USP monograph for 11 valsartan? 12 A I believe that the method was either 13 the same or very close, but I'm not -- I'm -- I'm 14 relying on memory. And if I wanted to make a 15 definitive statement, I'd want to look at those 16 two things side by side. But that's the way I 17 would say. 18 Q When you did your review, did you find 19 any difference in the methods that you wanted to 20 further investigate? 21 MR. HARKINS: 22 Object to form. Vague. 23 A No. There wasn't -- I did not notice 24 anything that seemed significant to me. Did not</p>	<p style="text-align: right;">Page 84</p> <p>1 whole question. Sorry about that. There's a 2 little delay. 3 MS. BOGDAN: 4 Q Sure. I'll repeat the question. 5 Is there part of the expert report 6 where you compare the Teva HPLC impurity method 7 to the USP impurity method? 8 A I -- I don't remember for positive 9 because I know I've thought about this, but I 10 don't want to confuse what's in my brain that I 11 thought about it versus what I actually recorded 12 in the expert report. Is there something you 13 could point me to that might be associated with 14 that? 15 Because I did make a comparison to the 16 sensitivity of the methods. And, so, I'd like to 17 see the exact -- where I said what methods I was 18 referring to and what -- how I -- how I framed 19 the sensitivity issue. 20 MR. HARKINS: 21 Take a moment to look at your report. 22 Okay? 23 THE WITNESS: 24 Okay. I'm looking through my report</p>
<p style="text-align: right;">Page 83</p> <p>1 notice any differences that seemed significant to 2 me. I don't recall any. 3 MS. BOGDAN: 4 Q Did you take any notes of any 5 differences that you discovered when looking at 6 the Teva impurity HPLC method versus the USP 7 impurity HPLC method? 8 MR. HARKINS: 9 Object to form. Vague. 10 A Did I take any notes? I think -- I 11 can't remember. Did I address this in the expert 12 report? I -- I feel like maybe I did. But I -- 13 I don't know if I took notes on any -- anything. 14 Can you -- can you reask the question 15 so I'm accurate? I may want to look at my expert 16 report to kind of make sure. 17 MS. BOGDAN: 18 Q ...expert report where you compare the 19 Teva HPLC impurity method to the USP impurity 20 method? 21 MR. HARKINS: 22 Rosemarie, looked like you were 23 speaking for a bit before we got the audio coming 24 through. I just want to make sure we have the</p>	<p style="text-align: right;">Page 85</p> <p>1 briefly here. I think I might be able to find 2 it. 3 MS. BOGDAN: 4 Q Well, my question would be, which, 5 Dr. Baertschi, looking at your report would allow 6 you to answer, is there a part of your report 7 where you evaluate the HPLC method of Teva as it 8 compares to the USP monograph method? 9 A I -- I don't think I have a direct 10 comparison of Teva to USP, the analytical methods 11 for those, in my expert report. I hope I'm not 12 wrong, but I'm not seeing anything that is like a 13 direct comparison. 14 Q When offering your opinions with regard 15 to what impurities HPLC testing would identify, 16 were you looking at the Teva HPLC testing method 17 or the USP HP- -- 18 A I looked at -- 19 Q -- -LC impurity testing method? 20 A I looked at both, and the -- the 21 wavelength of detection, the limit of disregard, 22 the limit of detection, the reporting levels were 23 very comparable. And my comparison was to try to 24 assess could these methods have detected the --</p>

<p style="text-align: right;">Page 86</p> <p>1 the levels of -- levels of NDMA or NDEA at the PM 2 levels being discussed. And that was the point 3 of my assessment. 4 And my determination was they're -- 5 they're pretty comparable and they have pretty 6 similar specifications for the methods. 7 But I'm not seeing that I did a direct 8 comparison in my expert report. It didn't seem 9 worthy of that. I didn't think there was a 10 contention around whether or not the method could 11 have detected low levels of NDMA or NDEA. 12 I'm -- I'm looking now at a -- 13 MR. HARKINS: 14 Wait for a question, unless you're -- 15 A I'm still continuing my answer, since 16 she paused for a long time. I'm finding 17 something now. 18 Paragraph 32, I'm looking at far -- I 19 did a compar- -- similar conclusions about the 20 ability of -- in paragraph 32, about the ability 21 of compendial impurity methods to detect low 22 levels of NDMA or NDEA can be made by looking at 23 the pharmacopeial methods listed in USP for 24 valsartan tablets, valsartan amlodipine tablets,</p>	<p style="text-align: right;">Page 88</p> <p>1 Q Did you do an analysis of the Teva HPLC 2 impurity method that was being used to evaluate 3 impurities in the valsartan finished dose 4 product? 5 MR. HARKINS: 6 Objection. Asked and answered. 7 A Yes. 8 MS. BOGDAN: 9 Q And you didn't discuss it in your 10 report? 11 MR. HARKINS: 12 Objection. Asked and answered. 13 A Apparently, I've already answered. 14 MR. HARKINS: 15 You have to answer again. 16 A Oh, I have to answer again. 17 I don't think so. I -- I already made 18 one mistake in remembering what was in there. I 19 hope I'm not making another one. But I don't see 20 it, so I don't -- I don't think I made a direct 21 commentary on the -- the Teva method in here. 22 MS. BOGDAN: 23 Q Now, for your work in this litigation, 24 you were retained by the Teva defendant; correct?</p>
<p style="text-align: right;">Page 87</p> <p>1 et cetera. 2 These analytical methods for impurities 3 utilize HPLC with UV detection for tablets, 4 valsartan tablets, with a level of -- with a 5 disregard for any peaks less than -- 6 So the answer to your question is yes, 7 I do do a comparison. It's in paragraph 32. 8 MS. BOGDAN: 9 Q And paragraph 32 is referring to the 10 USP method? 11 A Yes. I believe so. Because it says in 12 the last sentence, it says "it is clear that 13 these compendial methods are not appropriate for 14 detecting -- detecting and reporting of levels of 15 NDMA or NDEA at levels below 1,000 ppm, or .1 16 percent." 17 Q And is it in paragraph 32, then, you 18 discuss the HPLC method used by Teva? 19 A I don't know. I don't see any 20 specific reference to the method used by Teva in 21 my expert report, in that paragraph, and I'm not 22 seeing it anywhere else. I don't think that 23 changes my conclusions at all, and I think the 24 conclusions will hold.</p>	<p style="text-align: right;">Page 89</p> <p>1 A Correct. 2 Q And you're not working on behalf of any 3 of the other defendants; correct? 4 A Correct. 5 Q And, so, you're not offering any of 6 your opinions on behalf of the other defendants 7 in this litigation, are you? 8 MR. HARKINS: 9 Object to the form to the extent it 10 calls for a legal conclusion. 11 You can answer. 12 A I don't know the extent to which my 13 testimony will be used. I -- I don't understand. 14 MS. BOGDAN: 15 Q I'm not asking about it being used. 16 I'm being -- as far as you offering opinions in 17 this case, you're offering those opinions on 18 behalf of Teva; correct? 19 A Correct. 20 Q And do your opinions apply to all the 21 plaintiffs in this litigation? 22 MR. HARKINS: 23 Object to the form of the question. 24 You can answer if you know.</p>

<p style="text-align: right;">Page 90</p> <p>1 A Can you repeat the question?</p> <p>2 MS. BOGDAN:</p> <p>3 Q Do your opinions apply to all of the</p> <p>4 plaintiffs in this litigation?</p> <p>5 MR. HARKINS:</p> <p>6 Same objection, to the extent it calls</p> <p>7 for a legal conclusion.</p> <p>8 You can answer.</p> <p>9 A I -- I don't know. I don't know the</p> <p>10 details -- I didn't review all of the defendants'</p> <p>11 materials or methods, or -- so I -- I don't know</p> <p>12 what is applicable and what is usable --</p> <p>13 MS. BOGDAN:</p> <p>14 Q Okay.</p> <p>15 A -- and how -- how extensive that goes.</p> <p>16 Q Do your opinions apply to all potential</p> <p>17 class members?</p> <p>18 MR. HARKINS:</p> <p>19 Objection to the extent it calls for a</p> <p>20 legal conclusion.</p> <p>21 You can answer.</p> <p>22 A I would -- I would say the same kind of</p> <p>23 answer. I don't know legally what -- where the</p> <p>24 limits of my testimony are useful for or can be</p>	<p style="text-align: right;">Page 92</p> <p>1 length of time to see if they ever develop any</p> <p>2 kind of diseases associated with their ingestion</p> <p>3 of valsartan.</p> <p>4 Q Do your opinions vary depending on</p> <p>5 which type of plaintiff?</p> <p>6 MR. HARKINS:</p> <p>7 Objection to the extent it calls for a</p> <p>8 legal conclusion.</p> <p>9 A My opinions are -- I don't want to use</p> <p>10 the word "agnostic" to those, but it's sort of</p> <p>11 independent. It's not affected by any of those</p> <p>12 classes.</p> <p>13 MS. BOGDAN:</p> <p>14 Q So your opinions don't vary depending</p> <p>15 on how much valsartan a potential class member</p> <p>16 paid for?</p> <p>17 MR. HARKINS:</p> <p>18 Object to form. Facts not in evidence.</p> <p>19 You can answer if you know.</p> <p>20 A No, they don't. It's independent.</p> <p>21 They don't seem to be over -- my opinions don't</p> <p>22 seem to have a dependence on that information you</p> <p>23 just specified.</p> <p>24 MS. BOGDAN:</p>
<p style="text-align: right;">Page 91</p> <p>1 applied against.</p> <p>2 MS. BOGDAN:</p> <p>3 Q Do you have an understanding of the</p> <p>4 proposed class or classes that the plaintiffs</p> <p>5 seek to certify in this litigation?</p> <p>6 MR. HARKINS:</p> <p>7 Objection to the extent it calls for a</p> <p>8 legal question. You can answer to your</p> <p>9 understanding.</p> <p>10 A I have a recollection of a layman's</p> <p>11 understanding of there being three classes of</p> <p>12 plaintiffs.</p> <p>13 MS. BOGDAN:</p> <p>14 Q And what is your understanding of those</p> <p>15 classes?</p> <p>16 A As I recall, there's one that maybe are</p> <p>17 seeking their money back for the product because</p> <p>18 they feel it wasn't effective, maybe. I think</p> <p>19 there was a second maybe seeking damages for</p> <p>20 cancers or diseases that have incurred</p> <p>21 potentially as a result of their taking of</p> <p>22 valsartan, and I believe there was a third that</p> <p>23 had to do with paying -- getting their medical</p> <p>24 monitoring for the rest of their life or some</p>	<p style="text-align: right;">Page 93</p> <p>1 Q So you would agree that your opinions</p> <p>2 apply equally to all the different types of</p> <p>3 plaintiffs?</p> <p>4 MR. HARKINS:</p> <p>5 Object to the form to the extent it</p> <p>6 calls for a legal conclusion.</p> <p>7 A I -- I feel like my opinions are not</p> <p>8 dependent on, not derived from, not overlapping</p> <p>9 with the claims. So I don't feel that there's</p> <p>10 any variation as a function of what one of --</p> <p>11 Either of these three claims doesn't</p> <p>12 affect my expert report or my opinions.</p> <p>13 MS. BOGDAN:</p> <p>14 Q Okay. Did counsel ask you to make any</p> <p>15 assumptions for purposes of your report?</p> <p>16 A Not that I can recall. Assumptions,</p> <p>17 you know, no. I can't think of any.</p> <p>18 Q Did they ask you to rely on the</p> <p>19 opinions of any other expert for purposes of your</p> <p>20 report?</p> <p>21 A No. Well --</p> <p>22 MR. HARKINS:</p> <p>23 Just -- just to the extent that your</p> <p>24 answer would reflect any discussions with</p>

<p style="text-align: right;">Page 94</p> <p>1 counsel, I'm going to instruct you not to answer. 2 But -- 3 THE WITNESS: 4 Yeah. 5 MS. BOGDAN: 6 Q Let me ask you this question. I'll ask 7 it in a different way just to avoid the 8 objection. 9 Do you rely on the opinions of any 10 other experts for purposes of rendering your 11 opinions in this case? 12 A No. When you said "experts," I was 13 thinking -- you're probably thinking about 14 experts that have been in this case. I'm 15 thinking about a lot of experts that I've cited 16 in my literature that I consider experts in the 17 field. And, so, I've cited -- the literature I 18 cited and the experts that I have cited in my 19 expert report are -- definitely have influenced 20 my opinions as I've derived from the referee 21 literature. But I don't -- I don't think there's 22 any expert opinions that have affected my expert 23 report conclusions or opinions. 24 Q You're right. The question I was</p>	<p style="text-align: right;">Page 96</p> <p>1 makes it a nitrosamine; correct? 2 A Yes. N-nitrosamine. There are 3 nitrosamines that are not attached to nitrogen. 4 So it's N-nitrosamine, to be completely correct. 5 Q And what type of bond is formed between 6 the nitrogen and the oxygen in an N-nitrosamine? 7 A Wow. This is getting, like, organic 8 chemistry test, which is good. I love it. 9 It's a double bond, but it has single 10 bond characters. So it's -- it's N, single bond, 11 N, double bond, O. But there's double bond 12 character in the NN bond and there's single bond 13 character, which means you can have rotation 14 about the NN bond, and it can be inhibited 15 because of the partial double bond character in 16 it and the partial single bond character in the 17 oxygen. 18 So you can get two atropisomers, which 19 means inhibition due to rotation about a single 20 bond. And I learned that back in 1986 from 21 Stephen Hecht at a presentation at Vanderbilt 22 University. 23 Q And that structure is what's in common 24 with all N-nitrosamines; correct?</p>
<p style="text-align: right;">Page 95</p> <p>1 asking is whether or not, for your opinions in 2 this litigation, you were relying on the opinions 3 of any other experts that have been retained in 4 this litigation. 5 A No. 6 Q ...nitrosamines? 7 A We only caught "nitrosamines." 8 Q Sorry. What are nitrosamines, in an 9 organic chemistry sense? 10 A This is too much fun for an organic 11 chemist, but I'll take it anyway. 12 Nitrosamines are compounds that have a 13 functional group on them of nitrogen connected to 14 a nitrogen connected to an oxygen. And there can 15 be anything -- any things coming off the nitrogen 16 that's connected to a nitrogen that's connected 17 to an oxygen. So in the case of NDMA, it's 18 dimethyl. 19 But you can have any kind of 20 substituent, so there can be a huge diversity of 21 N-nitrosamines as long as there's that one 22 subgroup or functional group attached to the 23 molecule. 24 Q And it is that functional group that</p>	<p style="text-align: right;">Page 97</p> <p>1 A Yes. Although that cis-trans, that 2 different orientation, the relative amounts of 3 the sister trans of the two orientations can vary 4 as a function of what's on the rest of the 5 molecule. But I'm being nauseatingly detailed 6 there. So the answer is yes. 7 Q And you mentioned attending a 8 presentation or lecture by Dr. Hecht back in 9 1986, roughly? 10 A Roughly. It was when I was in graduate 11 school, so I'm guessing on the year. I just know 12 the rough -- rough years. I think it was '86. 13 Q And, so, nitrosamines were being 14 studied in the '80s; correct? 15 A Yes. He was studying it in smoke, as I 16 recall, if I'm recalling correctly, what smokers 17 inhaled. 18 Q ...nitrosamines formed? 19 A You cut out, so I only heard 20 "nitrosamines formed." 21 Q How are nitrosamines formed? 22 A They're usually -- there is a variety 23 of ways. You can form them from oxidation of -- 24 of an azide, but -- but from the meaningful to</p>

<p style="text-align: right;">Page 98</p> <p>1 this case and to most pharmaceutical concerns --</p> <p>2 most, I would say -- is that they form as a</p> <p>3 result of a nitrosating reagent reacting with,</p> <p>4 typically, a secondary amine.</p> <p>5 But it can also happen with a tertiary</p> <p>6 amine. It can also happen with some other</p> <p>7 amines. But it's primarily secondary amines and</p> <p>8 a nitrosating reagent.</p> <p>9 Q It's recognized that it can also happen</p> <p>10 with interaction with a tertiary amine or other</p> <p>11 amines; correct?</p> <p>12 A Yes. Just typically much slower, and</p> <p>13 they're oftentimes, depending on the</p> <p>14 circumstance, much less stable.</p> <p>15 Q Do you agree that nitrosamines are</p> <p>16 mutagenic?</p> <p>17 A Not all nitrosamines are mutagenic.</p> <p>18 Q Do you agree that NDMA is mutagenic?</p> <p>19 A Yes. Mutagenic being defined by Ames</p> <p>20 positive result in the Ames test, Ames</p> <p>21 mutagenicity test, yes.</p> <p>22 Q Do you agree that NDMA is genotoxic?</p> <p>23 MR. HARKINS:</p> <p>24 Object to form. Scope.</p>	<p style="text-align: right;">Page 100</p> <p>1 human carcinogen?</p> <p>2 A I believe that's the classification</p> <p>3 that they use for NDMA. That sounds correct.</p> <p>4 Q Do you agree that NDEA is a probable</p> <p>5 human carcinogen?</p> <p>6 A Can I say "same answer" and that be</p> <p>7 good enough?</p> <p>8 Q I'll ask -- I'll ask you the question</p> <p>9 again.</p> <p>10 Do you agree that NDEA is a probable</p> <p>11 human carcinogen?</p> <p>12 A I believe that's the -- the</p> <p>13 classification that goes with NDEA. That sounds</p> <p>14 correct.</p> <p>15 Q Do you agree with the classifications</p> <p>16 of probable human carcinogens for NDMA and NDEA?</p> <p>17 MR. HARKINS:</p> <p>18 Object to form. Scope.</p> <p>19 A I have no reason to dispute it, and I'm</p> <p>20 not a trained toxicologist to be able to dispute</p> <p>21 it. So I have no disagreement with that.</p> <p>22 MS. BOGDAN:</p> <p>23 Q Are you familiar with IARC?</p> <p>24 A Infrared?</p>
<p style="text-align: right;">Page 99</p> <p>1 You can answer.</p> <p>2 A Yes. Genotoxic is a -- mutagenic is a</p> <p>3 subset of genotoxic. So if something is</p> <p>4 mutagenic, it's also genotoxic. But there are</p> <p>5 genotoxic compounds that are not mutagenic. So,</p> <p>6 yes, it's also genotoxic.</p> <p>7 MS. BOGDAN:</p> <p>8 Q Do you agree that NDEA is genotoxic?</p> <p>9 MR. HARKINS:</p> <p>10 Same objection.</p> <p>11 A The same answers that I gave for NDMA</p> <p>12 would apply to NDEA.</p> <p>13 MS. BOGDAN:</p> <p>14 Q Oh, you agree that NDEA is genotoxic?</p> <p>15 A Yes. But when you said -- yes. From a</p> <p>16 technical classification, yes.</p> <p>17 Q Okay. And you agree that NDEA is</p> <p>18 mutagenic?</p> <p>19 A Yes. In the general term, yes.</p> <p>20 Q Do you agree that NDMA is a carcinogen?</p> <p>21 A Agree that it's a -- a known animal</p> <p>22 carcinogen and speculated or postulated human</p> <p>23 carcinogen.</p> <p>24 Q Do you agree that NDMA is a probable</p>	<p style="text-align: right;">Page 101</p> <p>1 Q IARC.</p> <p>2 A I-A-R-C. I thought you were using an</p> <p>3 abbreviation for infrared. I'm vaguely familiar</p> <p>4 with it, the committee that -- you know, for</p> <p>5 deciding or classifying the toxicology of</p> <p>6 chemicals and maybe classifying them as</p> <p>7 cancer-causing. I'm not exactly sure of the</p> <p>8 charter or what they exactly do, but I have heard</p> <p>9 of it and seen it.</p> <p>10 Q IARC stands for the International</p> <p>11 Agency For Research on Cancer; correct?</p> <p>12 A That sounds correct.</p> <p>13 MS. BOGDAN:</p> <p>14 If we could bring up the IARC</p> <p>15 monograph, 1978.</p> <p>16 (DEPOSITION EXHIBIT NUMBER 8</p> <p>17 WAS MARKED FOR IDENTIFICATION.)</p> <p>18 MR. HARKINS:</p> <p>19 Wait for the question.</p> <p>20 THE WITNESS:</p> <p>21 I see it on the screen, and it's still</p> <p>22 coming up. It's almost up on my big screen.</p> <p>23 MR. HARKINS:</p> <p>24 It's pretty large, but it's coming up.</p>

<p style="text-align: right;">Page 102</p> <p>1 THE WITNESS: 2 Yeah, it is. 314 pages long, and I can 3 see the first page. 4 MS. BOGDAN: 5 Q Okay. Well, let's just wait for it 6 to -- 7 A It's up. 8 Q -- to load. 9 A It's all loaded. It's good. 10 Q You can see it? 11 A Yes. 12 MS. BOGDAN: 13 Okay. If we could go to page 36. And 14 it's numbered in the bottom left corner, for the 15 tech. 16 A Yes. I'm on that page. 17 MS. BOGDAN: 18 Oh, that's 96. 19 A 36, not 96? Is that 96, not 36? 20 MS. BOGDAN: 21 Q The number, page number in the 22 document. There we go. I see it up on my 23 screen. 24 A Okay. So you can tell where I'm at.</p>	<p style="text-align: right;">Page 104</p> <p>1 N-nitrosodimethylamine (Fridman, et al., 1971.) 2 Q Does it say pH yields 3 N-nitrosodimethylamine? 4 A Yes. I believe I said that. 5 MR. HARKINS: 6 What does that mean? 7 THE WITNESS: 8 Oh. N-nitrosodimethylamine. 9 MS. BOGDAN: 10 Q Okay. So do you agree with that 11 sentence? 12 A Yes. And I have no reason to dispute 13 it. 14 Q And, so, you agree that the reaction of 15 dimethylamine hydrochloride with sodium nitrite 16 at an acidic pH yields N-nitrosodimethylamine? 17 A NDMA -- yes. 18 Q And that's well established in 19 chemistry? 20 A Yes. It's been established and -- and 21 I don't know how to classify "well," but I don't 22 think there's any controversy about it. 23 Q If we could go to page 40. It's four 24 ahead of where we are now.</p>
<p style="text-align: right;">Page 103</p> <p>1 That's good. 2 Q "The observation of severe liver 3 disease" is where it starts. 4 A Show me where on the screen. 5 Okay. That's helpful. 6 Q Yep. 7 A Am I on the wrong page? 8 Q It's page 36 in the bottom left-hand 9 corner. 10 A That's where I was. 11 Q Not of the PDF but of the data plate. 12 A Right. That's where I was, on page 36 13 in the bottom left-hand corner, but I'm getting 14 back there. 44... 15 Q And, actually, I'm gonna be asking you 16 about the third paragraph on that page that 17 starts with "It has been known since 1865." 18 A Okay. So I'm -- I'm with you, and I 19 can see both screens. 20 Q Okay. Can you read that first sentence 21 that starts with "It has been known since"? 22 A "It has been known since 1865 that the 23 reaction of dimethylamine hydrochloride with 24 sodium nitrite at an acidic pH yields</p>	<p style="text-align: right;">Page 105</p> <p>1 A I'm there now. 2 Q Okay. And this monograph was published 3 in 1978. But if you could read the first couple 4 sentences of the paragraph that begins with "Most 5 of." 6 A "Most of the chemical and physical 7 properties of the nitrosamines described in these 8 monographs were taken from Druckrey, et al., 9 1967. The principal techniques employed for the 10 analysis of volatile N-nitrosamines have been 11 described in a recent publication, Preussmann, 12 et al., 1978." 13 Q Are you familiar with that Preussmann 14 study? 15 A I have seen it. I wouldn't say I'm 16 familiar with it, but I have seen it. 17 Q Are you familiar with the Ruckrey [sic] 18 study, or Druck- -- if it's pronounced with the 19 D, making it Druckrey study? 20 A I'm not sure I've ever looked at the 21 Druckrey study. 22 Q Would you read the next sentence? 23 A "The relative merits of high and 24 low-resolution mass spectrometry are discussed,</p>

<p style="text-align: right;">Page 106</p> <p>1 since use of mass spectrometry as a confirmatory 2 technique is particularly important." 3 Q Do you agree that the use of mass 4 spectrometry is a confirmatory technique which is 5 important -- 6 MR. HARKINS: 7 Object to form. Vague. 8 MS. BOGDAN: 9 Q -- in evaluating volatile 10 N-nitrosamines? 11 MR. HARKINS: 12 Same objection. 13 A I agree that the use of mass 14 spectrometry as a -- as a confirmatory technique 15 or as a technique is -- is particularly 16 important, yes. 17 MS. BOGDAN: 18 Q Okay. If we could go to page 83, so 19 Dr. Baertschi can orient himself, which is the 20 part of the monograph that talks about 21 N-nitrosodiethylamine. 22 A Yes, I -- I see it. 23 Q Okay. And I'm actually just going to 24 bring you right to --</p>	<p style="text-align: right;">Page 108</p> <p>1 Q Now, you used a term about the 2 molecular weight that was very much a chemistry 3 term, something about the characteristics of the 4 molecule. You said based on how low the 5 molecular weight is and the "blank" 6 characteristics of the molecule. 7 A I think I said aliphatic. 8 Q That's what you said. And I know that 9 the stenographer is gonna have difficulty with 10 that word. Could you -- I don't know if you can 11 spell it, but if you could also then tell us what 12 it means. 13 A Aliphatic is A-L-I-P-H-A-T-I-C, and it 14 has to do with, instead of nitrogen having two 15 hydrogens on it, for example, it has what -- a 16 two-carbon unit -- two two-carbon units coming 17 off of it, and they're saturated, which means 18 they have maximum number of hydrogens. 19 And when you have carbons with a 20 maximum number of hydrogens in a series, they're 21 called aliphatic series, and they tend to -- 22 until you get -- they tend to be volatile. And 23 then as you grow them, liquid, and, then, as you 24 grow them further, then they become semisolid and</p>
<p style="text-align: right;">Page 107</p> <p>1 Well, let me ask you this question. Is 2 N-nitrosodiethylamine a volatile chemical? 3 MR. HARKINS: 4 Object to form. Vague. 5 A It's described here as a yellow 6 volatile liquid with a boiling point of 177 7 degrees C. 8 MS. BOGDAN: 9 Q Do you know it to be a volatile 10 chemical? 11 A I don't know it to be a volatile 12 chemical, but I would presume it was somewhat 13 volatile based on how low the molecular weight is 14 and the aliphatic characteristics of the 15 molecule. But it would be -- 177 degrees boiling 16 point is not particularly volatile from a chemist 17 point of view. 18 Q Would you call it a semivolatile 19 chemical? 20 MR. HARKINS: 21 Object to the form. 22 A I'm okay with the description as yellow 23 volatile liquid. I have no dispute with that. 24 MS. BOGDAN:</p>	<p style="text-align: right;">Page 109</p> <p>1 then eventually solids. 2 But the character -- a chemist can look 3 at that and sort of take a guess at whether it 4 might be volatile or -- or not. It's -- it's an 5 incidental point that I don't see as being 6 important, but you can take it for what it's 7 worth. 8 Q Just wanted to make sure I asked what 9 the word was and what it meant. Okay. 10 A Yeah. 11 Q All right. If we could go to page 107 12 in this N-nitrosodiethylamine section, which 13 brings you down to a summary of the data reported 14 and evaluation. The 107 is in the bottom 15 right-hand corner of the document. 16 A Yeah, I -- I've got it. 17 Q Do you see where it says "summary of 18 data reported and evaluation"? 19 A I do see that. 20 Q Okay. And under experimental data, it 21 says "N-nitrosodiethylamine is carcinogenic in 22 all animal species tested." And then it gives a 23 list of all the different animal species. 24 A Yes, I see that.</p>

<p style="text-align: right;">Page 110</p> <p>1 Q Do you disagree with that statement?</p> <p>2 MR. HARKINS:</p> <p>3 Object to form. Scope.</p> <p>4 A No. I have no reason to disagree with</p> <p>5 it.</p> <p>6 MS. BOGDAN:</p> <p>7 Q Then if we could go to the bottom of</p> <p>8 this page where it says "evaluation," would you</p> <p>9 read the first sentence, please.</p> <p>10 A "There is sufficient evidence of a</p> <p>11 carcinogenic effect of N-nitrosodiethylamine in</p> <p>12 many experimental animal species. Although no</p> <p>13 epidemiological data were available, the</p> <p>14 N-nitrosodiethylamine should be regarded for</p> <p>15 practical purposes as if it were carcinogenic to</p> <p>16 humans."</p> <p>17 Q Do you agree with that statement?</p> <p>18 MR. HARKINS:</p> <p>19 Object to form. Scope.</p> <p>20 A What I agree with, the practical</p> <p>21 purposes means that you should treat it as -- as</p> <p>22 if it were, regardless of whether it's firmly</p> <p>23 established, because you take precautions for</p> <p>24 safety.</p>	<p style="text-align: right;">Page 112</p> <p>1 A NDEA I would describe as a small</p> <p>2 molecule.</p> <p>3 Q Okay. How would you describe NDMA as</p> <p>4 far as its molecular size?</p> <p>5 A Small. Slightly smaller than NDEA.</p> <p>6 Q Okay. And NDMA, is that also a</p> <p>7 volatile chemical?</p> <p>8 MR. HARKINS:</p> <p>9 Object to form. Vague.</p> <p>10 A It says here "yellow oily liquid."</p> <p>11 MS. BOGDAN:</p> <p>12 Q Okay. And, then, under G, volatility,</p> <p>13 what does it say?</p> <p>14 A Can you point me to where it says --</p> <p>15 Oh, volatility, down at the bottom.</p> <p>16 Q The very bottom of the page.</p> <p>17 A Yes, I see now. It was different order</p> <p>18 than NDEA. "Volatile; can be steam-distilled</p> <p>19 quantitatively." So, yes, it's classified as</p> <p>20 volatile. And I note that the boiling point is</p> <p>21 much less than NDEA. At 50 to 52 degrees C, a</p> <p>22 much lower boiling point.</p> <p>23 Q Do you disagree with the description of</p> <p>24 NDMA being volatile?</p>
<p style="text-align: right;">Page 111</p> <p>1 MS. BOGDAN:</p> <p>2 Q Do you agree with that statement?</p> <p>3 MR. HARKINS:</p> <p>4 Same objection.</p> <p>5 A I have no particular reason for --</p> <p>6 From a practical purpose, you would</p> <p>7 regard something as carcinogenic or highly toxic</p> <p>8 in some other fashion. You would treat it the</p> <p>9 same as with extreme care and all that. So, I --</p> <p>10 from a practical point of view, I don't have any</p> <p>11 contention with that sentence.</p> <p>12 MS. BOGDAN:</p> <p>13 Q All right. If we could move to page</p> <p>14 125 of the document, which is the part of the</p> <p>15 monograph that refers to N-nitrosodimethylamine.</p> <p>16 And, Doctor, N-nitrosodimethylamine is NDMA;</p> <p>17 correct?</p> <p>18 A Yes, correct, to my understanding.</p> <p>19 Q And we had just talked about NDEA.</p> <p>20 Would you describe NDEA as a small molecule,</p> <p>21 large molecule, or something else?</p> <p>22 A I'd describe --</p> <p>23 NDMA; right?</p> <p>24 Q NDEA.</p>	<p style="text-align: right;">Page 113</p> <p>1 MR. HARKINS:</p> <p>2 Object to form. Scope. Vague.</p> <p>3 A No. I don't disagree with the</p> <p>4 classification as volatile.</p> <p>5 MS. BOGDAN:</p> <p>6 Q Okay. If we can go to page 151, which</p> <p>7 is the summary of data reported and evaluation</p> <p>8 for NDMA.</p> <p>9 A Sorry. I'm probably doing the wrong</p> <p>10 way, scrolling down, and it's going slower. I'm</p> <p>11 trying to go fast. 147, 48.</p> <p>12 Q I'm directing you to the center of that</p> <p>13 page where it says, again, "summary of data</p> <p>14 reported and evaluation," similar to what we had</p> <p>15 for NDEA.</p> <p>16 A I am there.</p> <p>17 Q Okay. And under "experimental data,"</p> <p>18 do you see where it says "N-nitrosodimethylamine</p> <p>19 is carcinogenic in all animal species tested"?</p> <p>20 A I do see that.</p> <p>21 Q Do you know that to be the case?</p> <p>22 MR. HARKINS:</p> <p>23 Object to form. Scope. Speculation.</p> <p>24 You can answer.</p>

<p style="text-align: right;">Page 114</p> <p>1 A I don't know it personally. I know it 2 from reading it in general knowledge of what's -- 3 what I've seen in the literature over time. 4 MS. BOGDAN: 5 Q Do you, based upon your research and by 6 knowledge in reading in the literature, agree 7 that N-nitrosodimethylamine is carcinogenic in 8 all animal species tested, as far as you know? 9 MR. HARKINS: 10 Object to form. Outside the scope of 11 the expert report. Asked and answered. 12 A Yes. 13 MS. BOGDAN: 14 Q And jumping down to evaluation, which 15 is actually on the next page, page 152, would you 16 read the evaluation for NDMA? 17 A Do you want me to read that whole 18 paragraph or -- 19 Q Yes, please. 20 A Okay. Here -- here we go. 21 "There is sufficient evidence of a 22 carcinogenic effect of N-nitrosodimethylamine in 23 many experimental animal species. Similarities 24 in its metabolism by human and rodent tissues</p>	<p style="text-align: right;">Page 116</p> <p>1 Object to form. Scope. 2 A I don't know what you mean by "group." 3 MS. BOGDAN: 4 Q IARC has a -- a classification where it 5 groups the different chemicals according to 6 different definitions, group 1, group 2, group 7 2A, group 2B, group 3, group 4. 8 Are you aware of those types of 9 classifications for NDMA or NDEA? 10 MR. HARKINS: 11 Object to form. Scope. Foundation. 12 A I -- I have not researched this and I'm 13 not commenting on it in my expert report, and 14 I -- I don't have -- like, I'm not a 15 toxicologist, so I'm not completely aware of how 16 they've classified NDEA and NDMA. But I would 17 think it -- it would be apparent from reading the 18 material if we were looking at it. 19 MS. BOGDAN: 20 Q IARC has classified NDEA and NDMA as 21 group 2A, which is probably carcinogenic to 22 humans. Do you agree with that classification? 23 MR. HARKINS: 24 Object to form. Scope. Foundation.</p>
<p style="text-align: right;">Page 115</p> <p>1 have been demonstrated. Although no 2 epidemiological data were available (and efforts 3 should be directed toward this end), 4 N-nitrosodimethylamine should be regarded for 5 practical purposes as if it were carcinogenic to 6 humans." 7 Q Do you agree with that paragraph? 8 MR. HARKINS: 9 Object to form. Scope. Foundation. 10 A This is the same discussion as we had 11 with NDEA, and my conclusions would be the same, 12 so I hope I state it the same here, that I have 13 no issue with -- with the way it's stated; that 14 for practical purposes for -- to be extremely 15 cautious, that it should be handled as if it 16 were, in the same manner as a known carcinogen 17 would be. 18 MS. BOGDAN: 19 Q Thank you. 20 MS. BOGDAN: 21 If we could take that down, please. 22 Q Do you know what group IARC has 23 classified NDEA or NDMA in? 24 MR. HARKINS:</p>	<p style="text-align: right;">Page 117</p> <p>1 We're way outside anything in his expert report. 2 You can answer if you know. 3 A I don't have any reason to contest what 4 toxicologists and official organization have put 5 together. I've not researched the toxicology and 6 I've not -- not opined on it in my expert report. 7 MS. BOGDAN: 8 Q As part of your investigation into this 9 matter, did you look at the FDA's advice that it 10 gave regarding the valsartan NDMA and NDEA 11 contamination -- 12 MR. HARKINS: 13 Object to form. Scope. 14 MS. BOGDAN: 15 Q -- that was -- that was discovered? 16 A I have reviewed several EMA and FDA 17 documents as part of my general work consulting 18 for N-nitroso compounds and particularly for NDEA 19 and NDMA, and I'm familiar. But I -- I believe I 20 disclosed it in my references or materials 21 considered. But I certainly am aware of it just 22 in my general consulting practice. 23 Q When you say you "disclosed it in my 24 references or materials," what are you speaking</p>

<p style="text-align: right;">Page 118</p> <p>1 of disclosing?</p> <p>2 A Well, I tried to be comprehensive in</p> <p>3 what I disclosed in materials that I considered,</p> <p>4 but I don't know what your question really is</p> <p>5 getting at. So maybe help me.</p> <p>6 Q Okay. What I was asking is is -- I</p> <p>7 asked, as far as your investigation into this</p> <p>8 matter, if you reviewed the FDA's advice that it</p> <p>9 gave with regard to the valsartan NDMA and NDEA</p> <p>10 contamination --</p> <p>11 A Yes.</p> <p>12 Q -- and --</p> <p>13 A Sorry. I thought you were complete.</p> <p>14 Q Yeah, no. That's -- that's the</p> <p>15 question I asked.</p> <p>16 So I think, from your answer, that you</p> <p>17 were saying that you have reviewed it? Or you</p> <p>18 haven't reviewed it in your consulting capacity</p> <p>19 but perhaps reviewed it in your consulting</p> <p>20 capacity for others, not in connection with the</p> <p>21 work that you've done on this case?</p> <p>22 But I'll let you clear the answer up.</p> <p>23 I don't want it to be -- I don't want to</p> <p>24 mischaracterize or misconstrue your response.</p>	<p style="text-align: right;">Page 120</p> <p>1 put it in -- in this document or in citations.</p> <p>2 I don't know for sure. I don't</p> <p>3 remember. I'm not encyclopedic. I'm not an</p> <p>4 encyclopedia. I may have made a mistake, even.</p> <p>5 MS. BOGDAN:</p> <p>6 Let's pull up the FDA general advice</p> <p>7 letter and mark that as an exhibit.</p> <p>8 (DEPOSITION EXHIBIT NUMBER 9</p> <p>9 WAS MARKED FOR IDENTIFICATION.)</p> <p>10 MS. BOGDAN:</p> <p>11 Q And, Dr. Baertschi, you can let me know</p> <p>12 once it's up on your screen.</p> <p>13 A It's up on my screen.</p> <p>14 Q All right. Are you familiar with this</p> <p>15 general advice letter?</p> <p>16 A Yes. I believe I've seen this before.</p> <p>17 Q I'm going to bring you down to the</p> <p>18 third paragraph on the first page. And first</p> <p>19 sentence refers to IARC, which is the monograph</p> <p>20 that we just spoke about; correct?</p> <p>21 A Correct.</p> <p>22 Q Now, the second sentence reads, "In</p> <p>23 fact, N-nitroso compounds are identified as a,"</p> <p>24 quote, "cohort of concern in internationally</p>
<p style="text-align: right;">Page 119</p> <p>1 A When you -- when you say "it," the FDA</p> <p>2 has had more than one "it" come out about</p> <p>3 valsartan and nitrosamines and NDMA and NDEA, as</p> <p>4 has EMA. And, so, they're pretty much</p> <p>5 self-consistent.</p> <p>6 I've seen several things from the FDA</p> <p>7 and several things from EMA, and if there's a</p> <p>8 particular document you want to ask me and show</p> <p>9 me and say have you -- have you reviewed this</p> <p>10 "it," then I'm happy to look at it.</p> <p>11 But I -- I believe I'm pretty</p> <p>12 up to date on FDA disclosures about valsartan and</p> <p>13 others' relation to nitrosamine contamination.</p> <p>14 It's been a big, well-publicized issue in the</p> <p>15 industry.</p> <p>16 Q With regard to the FDA references that</p> <p>17 you're referring to, did you -- did you note the</p> <p>18 ones that you reviewed in your report or in your</p> <p>19 materials considered list if you reviewed them in</p> <p>20 connection with this matter?</p> <p>21 A I can't say for a hundred percent sure.</p> <p>22 I -- there are -- I can't list everything that --</p> <p>23 that I've seen over the last couple of years</p> <p>24 related to nitrosamines and guarantee that I've</p>	<p style="text-align: right;">Page 121</p> <p>1 harmonized guidance."</p> <p>2 Are you familiar with that term,</p> <p>3 "cohort of concern"?</p> <p>4 A Yes, I am.</p> <p>5 Q What does that term mean?</p> <p>6 A It refers to three classes of compounds</p> <p>7 that are known to be associated with particularly</p> <p>8 high mutagenicity responses such that members of</p> <p>9 those classes of compounds, those three classes,</p> <p>10 are considered to be -- the -- the thresholds for</p> <p>11 toxicological concern listed in ICH M7 is not to</p> <p>12 be used directly but only as a starting point to</p> <p>13 think about for the cohorts of concern.</p> <p>14 So the implication is that you would do</p> <p>15 a case by case and it would be lower than the TTC</p> <p>16 for typical mutagens that weren't part of the</p> <p>17 cohort of concern.</p> <p>18 Q When you say "lower," meaning that they</p> <p>19 would have a lower threshold for what would be</p> <p>20 permitted in a drug substance or drug product?</p> <p>21 A Correct.</p> <p>22 Q And when you say "lower threshold,"</p> <p>23 that means less of those particular chemicals</p> <p>24 would be allowed in the drug substance or drug</p>

<p style="text-align: right;">Page 122</p> <p>1 product; correct?</p> <p>2 MR. HARKINS:</p> <p>3 Object to form. Vague. Speculation.</p> <p>4 A Yes.</p> <p>5 MS. BOGDAN:</p> <p>6 Q That's because those compounds are</p> <p>7 associated with particularly high mutagenicity</p> <p>8 responses; correct?</p> <p>9 MR. HARKINS:</p> <p>10 Object to form. Vague.</p> <p>11 A Those classes of compounds, yes.</p> <p>12 There -- there can be individual compounds within</p> <p>13 those classes that aren't even mutagenic. But in</p> <p>14 the absence of that knowledge, you treat them as</p> <p>15 the part of the cohort of concern.</p> <p>16 MS. BOGDAN:</p> <p>17 Q So those compounds in the cohort of</p> <p>18 concern are known to be associated with</p> <p>19 particularly high mutagenicity responses?</p> <p>20 MR. HARKINS:</p> <p>21 Object to form. Vague. Asked and</p> <p>22 answered.</p> <p>23 A I think I just answered that, that</p> <p>24 within a particular class, such as N-nitroso</p>	<p style="text-align: right;">Page 124</p> <p>1 Same objection.</p> <p>2 A Yes. That's my understanding. I don't</p> <p>3 have personal knowledge. I only have knowledge</p> <p>4 I've derived from literature.</p> <p>5 MS. BOGDAN:</p> <p>6 Q And, so, NDMA and NDEA are part of the</p> <p>7 N-nitroso compounds that are identified in the</p> <p>8 cohort of concern; correct?</p> <p>9 A Correct.</p> <p>10 Q And, then, moving further in this</p> <p>11 paragraph, it says "ICH M7 recommends that known</p> <p>12 mutagenic carcinogens such as nitrosamine be</p> <p>13 controlled at or below the acceptable cancer risk</p> <p>14 level."</p> <p>15 Do you agree with that statement?</p> <p>16 MR. HARKINS:</p> <p>17 Object to form. Scope.</p> <p>18 A Well, it's a funny wording, "the</p> <p>19 acceptable cancer risk level," so I'm surprised</p> <p>20 it's in a document from the FDA. But the</p> <p>21 acceptable threshold or risk level, and, so, I --</p> <p>22 as defined by the threshold of toxicological</p> <p>23 concern, the threshold for toxicological concern</p> <p>24 for these two are lower than -- than those that</p>
<p style="text-align: right;">Page 123</p> <p>1 compounds, there are N-nitroso compounds that are</p> <p>2 not mutagenic at all that are in -- that are in</p> <p>3 N-nitroso compounds that are similar to other</p> <p>4 mutagenic compounds in their mutagenicity, and</p> <p>5 then there are some that are more potent than the</p> <p>6 typical mutagenic compounds list in the ICH M7</p> <p>7 class of compounds.</p> <p>8 So I'm just trying to straighten out</p> <p>9 that you said "those compounds," and that can be</p> <p>10 generalized too far, and I wanted to clarify what</p> <p>11 I meant.</p> <p>12 MS. BOGDAN:</p> <p>13 Q Okay. With regard to NDMA</p> <p>14 specifically, is that one of the N-nitroso</p> <p>15 compounds that is associated with particularly</p> <p>16 high mutagenicity response?</p> <p>17 MR. HARKINS:</p> <p>18 Object to form. Vague. Scope.</p> <p>19 A Yes.</p> <p>20 MS. BOGDAN:</p> <p>21 Q When you refer to NDEA, is that one of</p> <p>22 those N-nitroso compounds that is associated with</p> <p>23 a particularly high mutagenicity response?</p> <p>24 MR. HARKINS:</p>	<p style="text-align: right;">Page 125</p> <p>1 are not in the cohort.</p> <p>2 MS. BOGDAN:</p> <p>3 Q Do you agree that known mutagenic</p> <p>4 carcinogens such as nitrosamines should be</p> <p>5 controlled at or below the acceptable cancer risk</p> <p>6 level?</p> <p>7 MR. HARKINS:</p> <p>8 Object to form. Vague. Scope. Asked</p> <p>9 and answered.</p> <p>10 A If the acceptable cancer -- cancer risk</p> <p>11 level is the threshold of toxicological concern</p> <p>12 for these compounds, yes. I don't exactly know</p> <p>13 what they mean by acceptable cancer risk level,</p> <p>14 so that's -- that's my problem. I normally have</p> <p>15 seen toxicological threshold of toxicological</p> <p>16 concern and that that threshold is lower for</p> <p>17 these compounds. Throwing in the cancer risk is</p> <p>18 not what I'm used to seeing in thresholds.</p> <p>19 MS. BOGDAN:</p> <p>20 Q Do you agree that NDMA should be</p> <p>21 controlled in drug substances and drug products</p> <p>22 to be 96 nanograms or less?</p> <p>23 MR. HARKINS:</p> <p>24 Object to form. Scope.</p>

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1 A I agree that -- that -- that that is
 2 the level that's been set by FDA and EMA, as I
 3 understand it.
 4 MS. BOGDAN:
 5 Q And with regard to NDEA, do you agree
 6 that NDEA should be limited in drug products to
 7 96 or -- excuse me -- to 26.5 nanograms or less?
 8 MR. HARKINS:
 9 Object to form. Vague. Scope.
 10 A The same answer. I agree that that's
 11 the level that's been set by EMA and FDA.
 12 MS. BOGDAN:
 13 Q The next sentence reads, "Due to their
 14 known potent carcinogenic effects and because it
 15 is feasible to limit these impurities by taking
 16 reasonable steps to prevent or eliminate their
 17 presence, FDA has determined that there is no
 18 acceptable specification for nitrosamines in ARB
 19 API and drug product."
 20 Do you see that sentence?
 21 A I see that.
 22 Q Okay. Do you agree that it is feasible
 23 to limit NDMA and NDEA by taking reasonable
 24 steps?

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1 MR. HARKINS:
 2 Object to form. Vague. Outside the
 3 scope.
 4 A I agree that in the cases I know of,
 5 there -- it is feasible to limit the levels of
 6 those impurities by taking steps to prevent or --
 7 to prevent their presence or reduce.
 8 MS. BOGDAN:
 9 We can take that down.
 10 MR. HARKINS:
 11 Hey, Rosemarie, when you get to a good
 12 spot, we're gonna need a few minutes just to
 13 finalize our lunch plans. We won't take it right
 14 now. We just want to make sure we know when
 15 that's gonna get here so we can plan for around
 16 1:00 probably.
 17 MS. BOGDAN:
 18 I mean, if you want to take it right
 19 now, Steve, that's fine. I just took a document
 20 down. If it's just a few minutes and it will
 21 make things go smoother, that's fine.
 22 MR. HARKINS:
 23 Can we go off the record?
 24 VIDEOGRAPHER:

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1 Off record, 11:59 a.m.
 2 (OFF THE RECORD.)
 3 VIDEOGRAPHER:
 4 On the record, 12:22 p.m.
 5 MS. BOGDAN:
 6 Q Dr. Baertschi, I see a reference that
 7 you're somehow affiliated with David P. Elder's
 8 laboratory. Is that true?
 9 A Affiliated, no. He's a colleague, a
 10 friend. I don't even know -- I don't think he
 11 has a laboratory. He's a consultant now, as far
 12 as I know. So I do know David Elder.
 13 Q And how do you know him?
 14 A Presenting at conferences over many
 15 years, running into him. And then sort of as you
 16 start to run into multiple times --
 17 And he publishes some of the same
 18 things, and, so, we exchange -- have in the past
 19 exchanged email, you know, conversations and
 20 such.
 21 Q Have you ever worked on a project
 22 together with David Elder?
 23 A I believe I published a paper -- I
 24 don't know if I published two, but I'm pretty

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1 sure he was a co-author on one article, at least,
 2 that I published.
 3 Q As far as you know, you're not a member
 4 of David Elder's laboratory?
 5 A Correct.
 6 Q And, then, do you know of an entity by
 7 the name of ResearchGate?
 8 A Yes.
 9 Q Okay. And what is that entity?
 10 A That's an Internet site that houses --
 11 hosts referee journal articles for people to then
 12 host their publications in a way that's compliant
 13 with the copyright issues associated with -- so
 14 that you can then view somebody's research,
 15 request a paper if you see one of interest, that
 16 sort of thing.
 17 Q So are you, like, a member of
 18 ResearchGate or...
 19 A Well, in the same way that I'm a member
 20 of, like, Google Docs or --
 21 You know, I mean --
 22 Q Okay.
 23 A -- it's like -- you know, it's just
 24 a -- I have a site or whatever -- an account

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1 where I have a ResearchGate profile, and my
 2 publications and associated information is on
 3 there.
 4 Q So you participate in that platform.
 5 Is that a good way to summarize it?
 6 A Yes.
 7 Q What did you undertake to investigate
 8 when you were retained as an expert consultant in
 9 this matter?
 10 A I missed the first part of the
 11 question. What did you undertake -- what --
 12 something about --
 13 Q What did you undertake to investigate
 14 when you were retained as an expert consultant in
 15 this matter?
 16 MR. HARKINS:
 17 Object to form. Vague.
 18 A I believe I've stated that in my expert
 19 report. Should we -- should we look at that and
 20 see what it says that I was asked to create an
 21 expert report on? Because that's essentially
 22 what they asked me to do.
 23 In -- I think it says assignment 3 in
 24 my expert report at paragraph 11.

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1 MS. BOGDAN:
 2 Q Okay. And what's -- you're referring
 3 to the sentence that starts "Specifically"?
 4 A I have been retained by the Teva
 5 defendants.
 6 Q Uh-huh. And then the next sentence
 7 that starts "Specifically," does that give us
 8 information as to what investigation you
 9 undertook with regard to your work on this case?
 10 A Yeah. That's a representation of
 11 what -- what I was requested to do.
 12 Q Okay.
 13 A I don't know if that exact wording
 14 was -- the -- when they first approached me, you
 15 know, to -- to -- as a potential expert witness,
 16 but something along the lines of analytical
 17 expertise for -- for this -- yeah, as an
 18 analytical expertise.
 19 Q And what, with regard to your
 20 analytical --
 21 I'm assuming you're referring to
 22 analytical chemistry.
 23 A Yes.
 24 Q We're in the chemistry field; right?

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1 Is that where we are? Okay.
 2 A Yes.
 3 Q So with regard to your being retained
 4 as an analytical chemist, what were you asked to
 5 review? Or what did you review?
 6 MR. HARKINS:
 7 Answer to the extent it doesn't reflect
 8 conversations with counsel. But you can discuss
 9 generally.
 10 A Well, they provided me with a link to a
 11 lot of documents associated with this case, some
 12 testimony, some materials. I can't remember all
 13 of it. But, you know, there was some expert
 14 reports, some testimony, some references, some --
 15 the actual -- what do you call them? -- the suits
 16 or the legal documents that would say here's the
 17 suits in question. I don't know how -- the right
 18 word. So that kind of general information.
 19 And they -- they gave me broader ac- --
 20 very broad access and let me kind of go around to
 21 figure out what would be most useful to help. So
 22 in terms of what they provided me with, access to
 23 a lot of information. Folders.
 24 MS. BOGDAN:

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1 Q And upon you reviewing that information
 2 that you had access to, did you come up with a
 3 suggestion as to what your focus of your expert
 4 report would be?
 5 MR. HARKINS:
 6 Object to form. Vague. Legal
 7 conclusion.
 8 You can answer.
 9 A I don't -- I don't remember exactly how
 10 that transpired. I think it was generally can
 11 you -- I think there was some general request,
 12 some idea of, you know, can I comment as an
 13 expert on the -- the analytical methods used and
 14 the techniques used and -- and their viability
 15 for detection of nitrosamines, et cetera, and
 16 impurities in general.
 17 MS. BOGDAN:
 18 Q And, so, your focus, when reviewing the
 19 documentation, was on the testing methods that
 20 were being employed?
 21 A That was one of my -- yeah. That's
 22 probably my main focus. And -- but also getting
 23 background information on the field and
 24 understanding chemistry and making sure I

<p style="text-align: right;">Page 134</p> <p>1 understood that the -- the current expert reports 2 and -- and testimony that was available at the 3 time. 4 Q And understanding the chemistry was 5 important with regard to investigat- -- your 6 investigation into this case; correct? 7 A "The chemistry" is a vague term, but 8 understanding chemistry is -- is part of 9 understanding how to apply analytical technique. 10 So if you're using an analytical 11 technique that's -- you -- you -- you want to 12 understand the chemistry underneath it so that 13 you can better discern the utility of and 14 limitations of the analytical -- analytical 15 techniques used. 16 Q Now, you referred to your report, 17 paragraph 11, and I'm assuming when you were 18 referring to that paragraph, you actually, in 19 your report, stated what you were asked by 20 counsel to do? 21 A Yeah. It -- it -- it says that 22 clearly, "I was asked by counsel." 23 Q Okay. And could you read that sentence 24 of your report that answers the question as to</p>	<p style="text-align: right;">Page 136</p> <p>1 what site wouldn't affect my opinion. 2 Q When you say it wouldn't -- there 3 wasn't an issue in your mind as to what equipment 4 was available, why wouldn't that be important to 5 determining the testing capabilities available to 6 Teva? 7 A Well, because I -- my understanding 8 was, without definitively -- definitively -- 9 definitively confirming it, was that they -- they 10 would have various levels of instrumentation 11 available, but it wouldn't affect -- the 12 specifics of that wouldn't affect my opinion on 13 the general process for how -- for how you go 14 about releasing drug products that have 15 particular specifications associated with it and 16 when you would proceed to nonroutine 17 investigatory-type approaches, which would then 18 require different instrumentation. 19 Q All right. So if we break that down, 20 when you're talking about releasing drug products 21 that have particular specifications, what 22 instrumentation would be needed with regard to 23 testing that's required by particular 24 specifications, as you referred to? Is that a</p>
<p style="text-align: right;">Page 135</p> <p>1 what you were asked to do in this case as an 2 expert consultant? 3 A Yes. I'll read the sentence. It says 4 "Specifically, I was asked by counsel for Teva to 5 assess testing conducted by and testing 6 capabilities available to Teva during the 7 relevant time period and to review and respond to 8 the opinions presented by plaintiffs' class 9 certification experts." 10 Q And is that sentence accurate as to 11 what you were asked to do as a consultant in this 12 case? 13 A As far as I can recollect, yes, I 14 believe so. 15 Q Did you make inquiry as to what 16 analytical chemistry equipment Teva owned as of 17 the time that it was producing 18 valsartan-containing drugs? 19 A I did not specifically make inquiry as 20 to what they had available. I did see some 21 testimony on it or some documents associated with 22 that, and -- and there was no issue in my mind or 23 particular concern that I had to nail that down 24 to know exactly what equipment was available at</p>	<p style="text-align: right;">Page 137</p> <p>1 PLC impurity testing? 2 MR. HARKINS: 3 Object to form. Vague. 4 A Yes. If we focus on what I think is 5 the most relevant part for -- to discuss, it 6 would be the HPLC impurities testing. There are 7 other specification tests, visual and -- and 8 things that I don't want to go list through 9 listing a bunch of techniques or instruments that 10 you might use in order to deal with the other 11 release specification testing, but if we focus in 12 on the most relevant impurities one, it would be 13 HPLC with UV detection. 14 MS. BOGDAN: 15 Q And, then, in your response, you refer 16 to nonroutine investigation-type instruments. 17 What would those be? 18 MR. HARKINS: 19 Did you hear the full -- I lost the 20 last part of that question. 21 A I -- I -- it did fade out. I don't 22 want to assume because I think I read your lips, 23 but let's maybe repeat so that I didn't. 24 MS. BOGDAN:</p>

<p style="text-align: right;">Page 138</p> <p>1 Q I said: And, then, in your response, 2 you referred to nonroutine investigation-type 3 instruments. What would those be? 4 A Without limiting it or without trying 5 to be comprehensive, the most obvious and 6 relevant one would be HPLC attached to a mass 7 spectrometer with maybe variable capabilities, 8 because there are different type of mass 9 spectrometers. But something that would be 10 aligned with elucidating structures, detecting 11 and elucidating structures of unknowns that are 12 not part of the specifications or that -- 13 I'm sorry. I should have finished. 14 They can be part of the 15 specifications -- like, it could be an unknown 16 peak that crops up -- or it can be something 17 that -- 18 Well, that's what -- that's what it 19 would typically be, is an unknown peak or -- or, 20 for some reason, that triggers a follow-up to 21 investigate further, which you would need some 22 kind of spectroscopic help to nail down the 23 structure. 24 Q And that instrument would be mass</p>	<p style="text-align: right;">Page 140</p> <p>1 Object to form. Scope. Asked and 2 answered. 3 A I didn't make specific inquiry. I 4 presumed that they did, and -- I presumed that 5 they did. 6 MS. BOGDAN: 7 Q In your experience working for 8 pharmaceutical companies, is gas chromatography a 9 typical instrument that pharmaceutical companies 10 have in their arsenal? 11 A Yes. 12 Q In your work for pharmaceutical 13 companies, are mass spectrometers something they 14 usually have in their instrument arsenal? 15 MR. HARKINS: 16 Object to form. Vague to the extent 17 that -- "arsenal." 18 A Yeah. 19 I would -- I think interpreting -- I 20 would agree that, in general, mass -- mass 21 spectrometers, that firms would have -- firms 22 that can -- have laboratories typically would 23 have some kind of access somewhere in their 24 network to a mass spectrometer.</p>
<p style="text-align: right;">Page 139</p> <p>1 spectrometry or a mass spectra instrument? 2 A Yes. Not necessarily limited to, but 3 that's probably the workhorse or the primary tool 4 that you would first go to, typically. 5 Q And did Teva have a mass spec 6 instrument? 7 A I am pretty sure they did. 8 Q Now, you mentioned earlier in your 9 testimony, I believe, NMR testing. 10 A Yes. 11 Q Okay. Did Teva have that instrument 12 available? 13 MR. HARKINS: 14 Object to form. Scope. 15 A I do not know, did not confirm. But I 16 would presume that a typical large firm would 17 have somewhere in its -- a large pharmaceutical 18 firm, that they would have NMR access somewhere 19 in their firm. But I do not know. 20 MS. BOGDAN: 21 Q And what about gas chromatography? Did 22 you make inquiry as to whether Teva had gas 23 chromatography testing capabilities? 24 MR. HARKINS:</p>	<p style="text-align: right;">Page 141</p> <p>1 MS. BOGDAN. 2 Q ...valsartan API suppliers to Teva? 3 A Something cut out at the start. 4 Q Sorry. Who were the valsartan API 5 suppliers to Teva? 6 A I am aware of two: ZHP and Mylan. 7 Q Did Teva have quality agreements with 8 ZHP and Mylan -- 9 MR. HARKINS: 10 Object to form. 11 MS. BOGDAN: 12 Q -- for the API that was being supplied? 13 MR. HARKINS: 14 Object to form. It's outside the scope 15 of his expert report. 16 You can answer. 17 A Yeah. I didn't look into that. I 18 wasn't asked to look into that. I believe there 19 were other expert witnesses that did look into 20 that question. That wasn't the focus of my work 21 or expert report. I don't talk about that. 22 MS. BOGDAN: 23 Q So you aren't offering any opinions 24 with respect to quality agreements between Teva</p>

<p style="text-align: right;">Page 142</p> <p>1 and the API suppliers; correct?</p> <p>2 A I would agree with that. I...</p> <p>3 Q Do you agree that Teva, as the ANDA</p> <p>4 holder, was ultimately responsible for the</p> <p>5 safety, quality, and purity of the finished drug</p> <p>6 product that it sold?</p> <p>7 MR. HARKINS:</p> <p>8 Object to form. Scope of his expert</p> <p>9 report. Calls for a legal conclusion. Vague.</p> <p>10 You can answer if you have an opinion.</p> <p>11 A I don't -- I don't know technically who</p> <p>12 is, from a regulatory or legal point of view, who</p> <p>13 is ultimately responsible for sure. I know that</p> <p>14 there's an API manufacturer and there's a dosage</p> <p>15 form manufacturer, and I think that there are --</p> <p>16 I would think that there would be differences in</p> <p>17 responsibility, but it's -- it's a little bit out</p> <p>18 of my -- I didn't try to review or figure that</p> <p>19 out or nail that down. I didn't look into that</p> <p>20 aspect.</p> <p>21 MS. BOGDAN:</p> <p>22 Q Are you a regulatory expert?</p> <p>23 A I have regulatory expertise in that</p> <p>24 I've worked in the industry and been involved in</p>	<p style="text-align: right;">Page 144</p> <p>1 they -- they do what should be done, what is</p> <p>2 expected to be done for -- to ensure the safety,</p> <p>3 efficacy, and purity of their drug.</p> <p>4 MS. BOGDAN:</p> <p>5 Q Did you review the recall notices for</p> <p>6 the Teva product? And let me be more specific.</p> <p>7 Did you review the recall notices for the Teva</p> <p>8 valsartan-containing drugs?</p> <p>9 A I believe so. I mean, I'm familiar</p> <p>10 with the recalls, and I believe I looked at</p> <p>11 material in the list of things that I looked at</p> <p>12 dealing with that. There's so much discussion of</p> <p>13 it, I don't know what's an official document in</p> <p>14 terms of in my brain versus what -- where it was</p> <p>15 referred to by somebody else.</p> <p>16 I didn't review any documents with the</p> <p>17 idea like I'm a CGMP guy or I'm a -- I'm a</p> <p>18 quality, I'm reviewing. I wasn't reviewing the</p> <p>19 data for CGMP compliance and quality or</p> <p>20 regulatory aspects.</p> <p>21 Q And, so, you're not offering any</p> <p>22 opinions with regard to CGMPs in this case?</p> <p>23 A Well, I think some of my testimony</p> <p>24 overlaps with CGMPs because you're -- you're --</p>
<p style="text-align: right;">Page 143</p> <p>1 many regulatory submissions, NDAs and I&Ds over</p> <p>2 the years, thirty or more than that, but I've</p> <p>3 never worked in regulatory, never been my primary</p> <p>4 responsibility. So while I have some expertise</p> <p>5 and knowledge of it, I don't hold myself out as a</p> <p>6 regulatory expert.</p> <p>7 Q In your experience, based upon your</p> <p>8 years working in the pharmaceutical industry,</p> <p>9 what is your understanding as to the</p> <p>10 finished-dose manufacturer's responsibility for</p> <p>11 the quality of the API that's in their drug</p> <p>12 product?</p> <p>13 MR. HARKINS:</p> <p>14 Same objection. Outside the scope of</p> <p>15 his expert report. Vague. Facts not in</p> <p>16 evidence.</p> <p>17 You can answer.</p> <p>18 A My understanding is that they're</p> <p>19 responsible for ensuring the -- the</p> <p>20 specifications are met and making sure that</p> <p>21 quality has been -- you know, that -- that</p> <p>22 they're manufacturing according to CGMPs, that</p> <p>23 they're compliant with all regulatory agencies,</p> <p>24 that they're -- that they're competent and that</p>	<p style="text-align: right;">Page 145</p> <p>1 I'm looking at the analytical results in context</p> <p>2 of specifications that are part of the CGMP</p> <p>3 process. And, so, I wouldn't classify it as I'm</p> <p>4 not saying anything related to CGMPs and I'm</p> <p>5 not --</p> <p>6 I'm just not trying to look between</p> <p>7 companies, who's responsible for what, what</p> <p>8 quality system agreements were in place, that</p> <p>9 sort of thing.</p> <p>10 Q But to the extent that standards are</p> <p>11 involved with looking at the analytical chemistry</p> <p>12 and the testing that was being done on valsartan,</p> <p>13 then you would be reviewing and commenting on</p> <p>14 things like the USP monograph and potentially</p> <p>15 CGMP; correct?</p> <p>16 MR. HARKINS:</p> <p>17 Object to form. Vague. Compound.</p> <p>18 A It was compound. It sounded -- what</p> <p>19 you said seemed -- sounded pretty good. You</p> <p>20 threw in CGMP in there, and some of those terms</p> <p>21 were loaded. But I think, in general, looking at</p> <p>22 standards and how they made sure that their</p> <p>23 product complied to the standards and how they --</p> <p>24 the scientific and the technical carrying out and</p>

<p>Page 146</p> <p>1 aspect -- the scientific and technical aspects of 2 that, I was looking into. 3 MS. BOGDAN: 4 Q I want to ask the question another way. 5 One of the things that you did look to is to 6 whether or not Teva was complying to the 7 scientific -- scientific and technical 8 standards when manufacturing the finished-dose 9 product; correct? 10 MR. HARKINS: 11 Object to form. Vague. Scope. 12 A I'm a little puzzled by the -- by the 13 question. Maybe you could re- -- 14 MS. BOGDAN: 15 Q Okay. Well, when you were reviewing 16 this matter, were you looking to see if Teva 17 complied with the specifications for impurity 18 testing with the finished-dose product? 19 A Yes. I was. 20 Q And were you looking to see if Teva 21 complied with the other type of testing that 22 would be associated with the finished-dose 23 product? 24 MR. HARKINS:</p> <p>Page 147</p> <p>1 Object to form. Vague. 2 A When you say "other type," I'm 3 presuming you mean the other specification test, 4 the -- the quality attributes that are listed in 5 the specifications. 6 MS. BOGDAN: 7 Q Yes. I am. 8 A In that sense, yes, I -- I agree with 9 your question. 10 Q Did Teva recall all of its drug product 11 that was made with the ZHP API that was not 12 beyond the expiration date? 13 MR. HARKINS: 14 Objection. Scope. 15 A Yeah. I'm not sure I could answer 16 that. I think that there are other people who 17 have looked into that very -- you know, with a -- 18 with close eyes. I may have stumbled across 19 information related to that, but I didn't store 20 it in my brain, and I can't say confidently 21 absolutely. So I can't really -- I can't really 22 answer it. And I don't comment on it in my 23 report. 24 MS. BOGDAN:</p>	<p>Page 148</p> <p>1 Q So you didn't make any determination 2 with regard to the scope of the Teva recall that 3 involved API made with ZHP or made by ZHP? 4 MR. HARKINS: 5 Same objection. 6 A I -- I did not look into it myself. I 7 did read some testimony from Roger Williams, 8 maybe, I believe, that -- that talked about some 9 of that, but I -- again, I was looking through 10 that -- 11 Even that deposition, I was just 12 looking to familiarize myself with -- with what's 13 already known, and I didn't -- I wasn't looking 14 for information to try to store in my head 15 related to the recalls and whether or not they 16 were comprehensive. 17 MS. BOGDAN: 18 Q And would that be true for Mylan as 19 well? Did you make any determination as to 20 whether Teva recalled all of its drug product 21 made with the Mylan API? 22 A I did not make any determination on 23 that topic. 24 Q When the recalls were first announced,</p> <p>Page 149</p> <p>1 was Teva product included in the early recalls? 2 MR. HARKINS: 3 Object to form. Scope. Foundation. 4 A Say that again. Can you -- was Teva -- 5 I need to hear -- 6 MS. BOGDAN: 7 Q Was Teva product included in the early 8 recalls? 9 MR. HARKINS: 10 Same objection. Also vague. 11 A I don't know what "early recalls" means 12 in -- I -- 13 You know, while I've read material 14 related to dates and times of recalls and -- and 15 whether or not certain recalls were related to 16 which manufacturer, but I -- I wasn't -- I wasn't 17 evaluating the information in a way to make a 18 determination or to -- to gather in and -- and 19 hold in my brain and -- and understand related to 20 that. 21 MS. BOGDAN: 22 Q Do you know why Teva product was 23 recalled? 24 MR. HARKINS:</p>
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<p style="text-align: right;">Page 150</p> <p>1 Objection. Scope. Vague.</p> <p>2 A Well, I know that some -- that there</p> <p>3 were general recalls. It was widely published in</p> <p>4 the industry, and I -- I believe I've seen some</p> <p>5 information that -- that related to N-nitrosamine</p> <p>6 contamination or impurities present in -- in API</p> <p>7 material in mixed dosage forms for a variety of</p> <p>8 manufacturers.</p> <p>9 MS. BOGDAN:</p> <p>10 Q Do you know what nitrosamines were</p> <p>11 found in the Teva product that prompted the</p> <p>12 recall?</p> <p>13 A I know there were two separate</p> <p>14 instances or two separate N-nitrosamines. One</p> <p>15 was for NDMA impurities present, and the other</p> <p>16 was for NDEA impurities detected.</p> <p>17 Q And, to your recollection, those were</p> <p>18 two separate recalls?</p> <p>19 A Yes, I believe so. I'm not -- I'm not</p> <p>20 confident in that answer, but...</p> <p>21 Q Did you review the Teva testing</p> <p>22 information to see what the levels of NDMA were</p> <p>23 that were found in the Teva product?</p> <p>24 A Yes, I -- I saw a number of tables</p>	<p style="text-align: right;">Page 152</p> <p>1 weight of finished dose.</p> <p>2 Q Did you calculate the amount of NDMA</p> <p>3 that was found in the tablets?</p> <p>4 A I looked at how they calculated the</p> <p>5 NDMA translating from ppm to -- to weight units,</p> <p>6 and it looked correct. I mean, so that they</p> <p>7 could figure out how many nanograms were in a</p> <p>8 single dose so that they did compare that to --</p> <p>9 well, so that they could just understand the</p> <p>10 total number of nanograms in any given API or</p> <p>11 finished-dose product.</p> <p>12 So I saw that calculation. It looked</p> <p>13 right, and then I -- and I've seen many where</p> <p>14 they were just listing nanograms per gram, I</p> <p>15 believe.</p> <p>16 Q And those levels that you saw, were</p> <p>17 some of them above the acceptable intake level</p> <p>18 that's permitted by the FDA?</p> <p>19 A Yeah. Some -- the acceptable limit</p> <p>20 being 96 nanograms for -- per -- per daily dose.</p> <p>21 So there were, yes, instances of -- of the levels</p> <p>22 of NDMA being above that 96.</p> <p>23 Q And, then, the same question with</p> <p>24 regard to NDEA. Did you review any documents</p>
<p style="text-align: right;">Page 151</p> <p>1 and -- and data on the amounts of both</p> <p>2 nitrosamines in different studies and different</p> <p>3 tests for both the API and the finished-dose</p> <p>4 product.</p> <p>5 Q What was the range of NDMA levels that</p> <p>6 you saw were found in the Teva product?</p> <p>7 A Um, NDMA in Teva. I would say, from</p> <p>8 memory, pretty low, like maybe a tenth of a ppm,</p> <p>9 in that range, up to a few hundred ppm of NDMA in</p> <p>10 the finished-dose product, in general. There</p> <p>11 might have been a couple of outliers higher or</p> <p>12 lower. But, in general, in that .1 ppm to a few</p> <p>13 hundred.</p> <p>14 Q And in order to figure out the amount</p> <p>15 of nanograms of NDMA in a finished dose, from</p> <p>16 knowing the ppm, you would just take the part per</p> <p>17 million number and multiply it by the number of</p> <p>18 milligrams in the tablet to get the amount of</p> <p>19 nanograms in the finished dose?</p> <p>20 A I think nanograms per gram would be</p> <p>21 the, quote -- well, that's parts per billion.</p> <p>22 Nanograms per milligram, I think, would be ppm.</p> <p>23 But you'd translate it from -- you'd put the</p> <p>24 actual units on it, the nanograms per -- per</p>	<p style="text-align: right;">Page 153</p> <p>1 that showed the testing levels for NDEA in the</p> <p>2 Teva finished-dose product?</p> <p>3 A Yes.</p> <p>4 Q And were some of those levels in excess</p> <p>5 of the allowed acceptable daily intake as set</p> <p>6 forth by the FDA?</p> <p>7 A Yes. And I believe that level was 26.5</p> <p>8 nanograms per day, as I recall. And -- for NDEA.</p> <p>9 And the NDEA levels in some of the lots -- I</p> <p>10 believe it was from Mylan for the API and then</p> <p>11 for Teva in the finished-dose product -- were</p> <p>12 above 26.5.</p> <p>13 MS. BOGDAN:</p> <p>14 If we could please pull up the FDA</p> <p>15 notice from July 13th, 2018.</p> <p>16 (DEPOSITION EXHIBIT NUMBER 10</p> <p>17 WAS MARKED FOR IDENTIFICATION.)</p> <p>18 A Is that Exhibit 10?</p> <p>19 MS. BOGDAN:</p> <p>20 I believe we're on Exhibit 10, but I</p> <p>21 would ask the court reporter to just verify that</p> <p>22 for us.</p> <p>23 TRIAL TECH:</p> <p>24 That's correct.</p>

<p>Page 154</p> <p>1 THE WITNESS: 2 Yeah. I've got it up now on my screen 3 and both screens. 4 MS. BOGDAN: 5 Q Have you seen the FDA news release 6 before? 7 A Yes. 8 Q And directing your attention -- 9 And this is dated July 13, 2018; 10 correct? 11 A Correct. 12 Q Directing your attention to the second 13 page, under recalled products, it lists the 14 medicine and the company. 15 A Yes, I see that. 16 Q Does it list Teva Pharmaceuticals for a 17 few of the medicines, and, in particular, two? 18 A Yes. I see it for the third one down 19 and for the bottom one. 20 Q Now, directing your attention to the 21 paragraph, there's a note from Dr. Woodcock. Do 22 you see that quote? 23 A Yes, I do. 24 Q Okay. Were you familiar with</p>	<p>Page 155</p> <p>1 Dr. Woodcock? 2 A She's been a director -- she's been at 3 the FDA for a long time. I'm familiar with her 4 name. I met her a couple times. She -- just 5 in -- she wouldn't know me. 6 Q I was gonna say, have you ever met 7 Dr. Woodcock personally? 8 A Yes, but, like, a three-second 9 handshake with a bunch of other people. 10 Q Okay. 11 A So not really. 12 Q All right. And she says "We have 13 carefully assessed the valsartan-containing 14 medications sold in the United States and we've 15 found that the valsartan sold by these specific 16 companies does not meet our safety standards." 17 And then she goes on to say "This is 18 why we've asked these companies to take immediate 19 action to protect patients." 20 MR. HARKINS: 21 Is there a question? 22 MS. BOGDAN: 23 Q Do you -- is it your understanding that 24 that is why the FDA announced the recall of those</p>	<p>Page 156</p> <p>1 valsartan products? 2 MR. HARKINS: 3 Object to form. Outside the scope of 4 his expert report. 5 A As I read this here, that's, in the 6 context, what it -- what it appears to be saying, 7 that they -- and it's in a recall announcement, 8 and this is their explanation. 9 MS. BOGDAN: 10 If you could please take that down. 11 Q Did you review the specific Teva recall 12 announcements? 13 MR. HARKINS: 14 Object to form. Asked and answered. 15 A I think I've already answered that. 16 MS. BOGDAN: 17 Q Was the answer yes or -- or no or you 18 weren't sure? 19 A I'm not completely sure. I know I've 20 seen a lot of documents that have recall 21 information. So it -- if I had to say, it's 22 likely that I did, yes. I'm not sure. I can't 23 say for sure I've seen a specific document. 24 MS. BOGDAN:</p>	<p>Page 157</p> <p>1 And will you please put up the Teva 2 recall from July 17th, 2018? 3 (DEPOSITION EXHIBIT NUMBER 11 4 WAS MARKED FOR IDENTIFICATION.) 5 MS. BOGDAN: 6 Q Are you familiar with this company 7 announcement, Dr. Baertschi? 8 And if we could mark it. I believe 9 we're on Exhibit 11. 10 A It -- it looks familiar. I can't say. 11 Sometimes documents look familiar and I haven't 12 seen the exact document. But it -- 13 Q Okay. And this document is dated July 14 17th of 2018? 15 A Yes. 16 Q At the top, Teva Pharmaceuticals USA is 17 issuing a voluntary nationwide recall of 18 valsartan and valsartan hydrochlorothiazide 19 tablets. 20 A I see that. 21 Q And bringing you down onto the company 22 announcement, into the first paragraph, it says 23 that the impurity detected in the API is 24 N-nitrosodimethylamine.</p>
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<p>Page 158</p> <p>1 MR. HARKINS: 2 Is that a question? 3 MS. BOGDAN: 4 Q Is this the recall that you were 5 referring to earlier in your testimony where you 6 said you reviewed one recall that was for NDMA 7 and then another one for NDEA? 8 A Yes. This is apparently the one for 9 NDMA. 10 Q And, then, just directing your 11 attention to pages 2 through 5 of the document, 12 if we could go -- that's 2, page 2, and then page 13 3, and page 4, and page 5, does that list all of 14 the products that were recalled? 15 MR. HARKINS: 16 Object to form. Outside the scope. 17 A Yeah, I didn't -- I didn't look in to 18 verify that that's all the lots. I.. 19 That's, you know, somebody else's 20 responsibility. I think that's -- FDA can be 21 accountable for that. 22 MS. BOGDAN: 23 Q Okay. 24 A Or Teva. I guess Teva's the company</p> <p>Page 159</p> <p>1 announcement. 2 Q Right. 3 MS. BOGDAN: 4 Okay. Let's pull up the Teva recall 5 notice of November 27th, 2018. 6 (DEPOSITION EXHIBIT NUMBER 12 7 WAS MARKED FOR IDENTIFICATION.) 8 A Okay. 9 MS. BOGDAN: 10 Q Dr. Baertschi, can you -- is that up on 11 your screen yet? Okay. 12 A Yes. 13 Q Okay. Now, the reason for this 14 announcement, if you could look under the 15 summary, it says "due to the detection of NDEA." 16 A Yes, I see that. 17 Q Okay. Is this the recall announcement 18 that you were referring to when you said there 19 was one that was for NDEA? 20 A Yes. I don't know if this is the only 21 one that there was for NDEA, but, yeah, it's -- 22 it's a recall for NDEA. 23 Q Then, again, starting on page 3 of this 24 document, it lists the product and lots that are</p>	<p>Page 160</p> <p>1 under the recall; correct? 2 A Yes. 3 Q And it continues to list those until 4 page 5 of the document? 5 A Yeah. It looks -- that looks to be 6 true. I mean, that looks -- I agree with that. 7 Q Okay. 8 MS. BOGDAN: 9 If we could please pull up Teva 10 document that ends with 693423. I believe it's 11 number 14 in the document repository, if that's 12 helpful. 13 (DEPOSITION EXHIBIT NUMBER 13 14 WAS MARKED FOR IDENTIFICATION.) 15 MS. BOGDAN: 16 If we could actually move past the 17 Bates stamp first page to the second page. 18 THE WITNESS: 19 Is this Exhibit 12 or 13? 20 MS. BOGDAN: 21 Court reporter, what -- 22 THE COURT REPORTER: 23 It's number 13. 24 THE WITNESS:</p> <p>Page 161</p> <p>1 It's not come up yet on my screen. 2 MS. BOGDAN: 3 There's a blank page on the first part 4 of the exhibit that just has the Bates number 5 down low. So if you're seeing a blank on your 6 screen, maybe you can scroll down. 7 MR. HARKINS: 8 It's not showing in our exhibit box 9 here that we're refreshing. 10 THE WITNESS: 11 Now it's there. 12 MS. BOGDAN: 13 Okay. 14 THE WITNESS: 15 Okay. Got it. 16 MS. BOGDAN: 17 Q And if you can look at the second page, 18 which is really the first page of the -- of the 19 report. Have you seen this document before? 20 A It looks familiar, yes. I believe so. 21 Q And this is a -- a Teva document that 22 you can see on the top. 23 A Yes. 24 Q And the title of it is "valsartan</p>
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<p style="text-align: right;">Page 162</p> <p>1 analytical drug substance and drug product 2 testing results sourced from" -- and I'm gonna 3 say ZHP. 4 A Yes. 5 Q So if I could direct your attention to 6 table 1 in this document, which has the testing 7 results. And in table 1, it looks like they 8 tested three different lots of valsartan 9 320-milligram tablets. 10 A Yes. 11 Q And directing your attention down to 12 the results section, which is the row that says 13 "NDMA results in sample equivalent to one gram 14 valsartan ppm." 15 A I see that. 16 Q Okay. And what is the ppm acceptable 17 limit established by the FDA for NDMA? 18 MR. HARKINS: 19 Object to form. Scope. 20 You can answer. 21 A If I recall correctly, it's .3 ppm. 22 MS. BOGDAN: 23 Q That would be 0.3? 24 A Yes. But -- but I'm not absolutely 100</p>	<p style="text-align: right;">Page 164</p> <p>1 Q The weight of the tablet, including its 2 event. 3 A Yes. Yeah. 4 Q Now, just if we take the results for 5 the valsartan tablets that are in the third 6 column where it has NDMA results in sample 7 equivalent to one gram valsartan ppm of 61.2 -- 8 A Yes. 9 Q Now, if you take that 61.2 and you 10 multiply it by 320, which is the milligrams, you 11 get 19,584, which would be, when it's rounded, 12 19,600. 13 MR. HARKINS: 14 Object to form in terms of the math. 15 A Yeah. I'm not sure what's -- what's 16 going on -- I mean, what you're doing. I don't 17 perceive -- 18 MS. BOGDAN: 19 Q Let me ask this question. Based on 20 this table, how many nanograms of NDMA did they 21 find in the valsartan tablets that are in the 22 third column on the table? 23 A How many nanograms did they find? 24 MR. HARKINS:</p>
<p style="text-align: right;">Page 163</p> <p>1 percent. I'm calling that from memory. I don't 2 think it's 3. I believe it's .3. If that's 3 important, we should establish it. 4 Q Are all of the values in that column 5 higher than .3? 6 A Yes. 7 Q Now, the next column says "NDMA results 8 per tablet." Do you see that? 9 A Yes. 10 Q And those results are expressed in 11 micrograms? 12 A No. They're expressed in parts per 13 million. 14 Q Okay. So they're expressed in parts 15 per million per tablet? 16 A Yes. 17 Q Okay. And, then, how would you 18 calculate the amount of nanograms in each tablet? 19 A You'd have to know the -- the weight, 20 the total weight of the tablet, which I believe 21 is 320 milligrams. So -- 22 Q You'd have to -- you'd have to know the 23 dose of the API in the tablet; right? 24 A Right.</p>	<p style="text-align: right;">Page 165</p> <p>1 Object to form. Just noting that 2 Dr. Baertschi does not have a calculator. He's 3 being asked to do this math on the blank. 4 If you're comfortable performing that 5 calculation or if you need to ask for anything to 6 aid in it, let us know. 7 A Yeah. So if you'll allow me to think 8 out loud in -- much to my -- 9 I would -- I would say -- 10 So if you have 61.2 parts per million, 11 let's -- part per million per gram, and when you 12 adjust it to what's in a tablet, it's 19.6 parts 13 per million, that would be 19,600 nanograms per 14 gram, which is parts per billion, or 19.6 parts 15 per million compared to .3 parts per million 16 limit. 17 MS. BOGDAN: 18 Q So the 19.6 parts per million is 19 significantly higher than 0.3 parts per million 20 limit; correct? 21 MR. HARKINS: 22 Object to form. Scope. 23 A 19.6 is significantly higher than 0.3, 24 yes.</p>

<p>Page 166</p> <p>1 MS. BOGDAN:</p> <p>2 Q And, in fact, all of the lots tested</p> <p>3 that are shown in table 1 are higher than the 0.3</p> <p>4 parts per million limit; correct?</p> <p>5 A Yeah. I see six results per tablet</p> <p>6 that give it in results, NDMA per tablet, and all</p> <p>7 six of them are above the 0.3.</p> <p>8 Q And if I could direct your attention to</p> <p>9 table 2, which is on the next page of the</p> <p>10 document.</p> <p>11 A Yeah.</p> <p>12 And when I said six results, I was</p> <p>13 looking at tables 1 and 2. So my apologies. I</p> <p>14 was already jumping down to the next table. I</p> <p>15 looked at table 1 and 3 and table 2, and I added</p> <p>16 them together to get all six results are above</p> <p>17 .3.</p> <p>18 Q So the answer that you gave to my</p> <p>19 previous question incorporated the sets of</p> <p>20 results that are shown for the three lots that</p> <p>21 are in table 2 as well?</p> <p>22 A Yes.</p> <p>23 Q And they're also all over the limit;</p> <p>24 correct?</p>	<p>Page 168</p> <p>1 believe is marked as number 13 in the document</p> <p>2 repository, the Bates stamp number that ends with</p> <p>3 48605.</p> <p>4 (DEPOSITION EXHIBIT NUMBER 14</p> <p>5 WAS MARKED FOR IDENTIFICATION.)</p> <p>6 MR. HARKINS:</p> <p>7 This is going to be Exhibit 14 is what</p> <p>8 she's saying.</p> <p>9 MS. BOGDAN:</p> <p>10 If you could please mark this as an</p> <p>11 exhibit as well.</p> <p>12 Q So Exhibit 14 is an email from Claire</p> <p>13 Lyons at Teva. Do you know Claire Lyons?</p> <p>14 A I do not.</p> <p>15 Q Do you know any of the employees of</p> <p>16 Teva?</p> <p>17 A It's possible that I do, but I don't --</p> <p>18 I can't recall anybody that I know personally at</p> <p>19 Teva.</p> <p>20 Q Have you published any studies with a</p> <p>21 co-author who works for Teva?</p> <p>22 A Not that I know of.</p> <p>23 Q Have you published any studies with a</p> <p>24 co-author that works for Mylan?</p>
<p>Page 167</p> <p>1 A Correct.</p> <p>2 Q And if I could direct your attention to</p> <p>3 the conclusion section of this report provided by</p> <p>4 Teva, just to the last sentence in the first</p> <p>5 paragraph, which reads "The API analytical test</p> <p>6 results indicate that the ZHP valsartan API</p> <p>7 manufacturing process in place is expected to</p> <p>8 generate NDMA with levels above the FDA initial</p> <p>9 interim acceptable limit of NMT 0.3 parts per</p> <p>10 million."</p> <p>11 And my question is: Do you have any</p> <p>12 information, based upon your investigation in</p> <p>13 this case, that would result in you having an</p> <p>14 opinion that that sentence is not correct?</p> <p>15 MR. HARKINS:</p> <p>16 Object to form. Outside the scope.</p> <p>17 Vague.</p> <p>18 You can answer.</p> <p>19 A I have no information that would</p> <p>20 suggest that that is incorrect. I don't have --</p> <p>21 yeah. I don't have any information on that. But</p> <p>22 I -- I have no information to challenge it.</p> <p>23 MS. BOGDAN:</p> <p>24 If we could please pull up what I</p>	<p>Page 169</p> <p>1 A Not that I know of.</p> <p>2 Q Have you published any studies with a</p> <p>3 co-author that works for ZHP, Solco, or Princeton?</p> <p>4 A Not that I know of.</p> <p>5 Q In this email, Claire is writing to</p> <p>6 Sofia, and in her first sentence -- sentence she</p> <p>7 references a term "COfA." Do you see that?</p> <p>8 A Yes.</p> <p>9 Q Do you know what COfA stands for?</p> <p>10 A Certificate of analysis, I presume.</p> <p>11 Q And, then, in that same first</p> <p>12 paragraph, she uses a term, "CEP." Do you know</p> <p>13 what CEP means?</p> <p>14 A I'm not recollecting it at the moment,</p> <p>15 what CEP means, stands for.</p> <p>16 Q Now, directing you further down this</p> <p>17 exhibit, which is an email from Sofia Schwartz to</p> <p>18 Claire Lyons, which the one we just looked at is</p> <p>19 responding to, and in that email there is a</p> <p>20 summary of the analytical testing that Teva</p> <p>21 performed on 36 Mylan API batches.</p> <p>22 MR. HARKINS:</p> <p>23 And, Doctor, feel free to look at the</p> <p>24 full email in the Dropbox if that makes it</p>

<p>Page 170</p> <p>1 easier.</p> <p>2 A Yeah. I want to make sure I understand</p> <p>3 the sequence, which email was first, the</p> <p>4 June 2nd -- July 1. Okay. This email that we're</p> <p>5 looking at is July 1st. It predates the one we</p> <p>6 just looked at.</p> <p>7 MS. BOGDAN:</p> <p>8 Q And my understanding -- and please feel</p> <p>9 free to review the document -- but as Teva</p> <p>10 produced these, the most recent email is on the</p> <p>11 top, and then they go in reverse chronological</p> <p>12 order.</p> <p>13 A Okay.</p> <p>14 Q So did you review that analytical</p> <p>15 testing that Teva performed on the Mylan API</p> <p>16 batches?</p> <p>17 A Yes, I believe so. I don't know if</p> <p>18 it's specifically this, you know, these batches,</p> <p>19 but I reviewed a number of analytical results</p> <p>20 from Mylan and Teva, yeah.</p> <p>21 Q Sorry.</p> <p>22 A From --</p> <p>23 Sorry. I wasn't quite finished.</p> <p>24 I've reviewed a number of results that</p>	<p>Page 172</p> <p>1 companies and regulatory agencies have developed</p> <p>2 methods for testing specifically for NDEA or</p> <p>3 NDMA, and some have even combined both or</p> <p>4 multiple N-nitrosamines into a single procedure.</p> <p>5 So I think my answer is yes, but I -- I</p> <p>6 can't necessarily say I can recall a specific</p> <p>7 release of method that FDA granted at one time.</p> <p>8 Seems like they might have done more than one</p> <p>9 release. But...</p> <p>10 Q On the --</p> <p>11 A If you want me to look at the document,</p> <p>12 I'd be happy to.</p> <p>13 Q Did you review the methods that the FDA</p> <p>14 published for determining NDMA and NDEA in</p> <p>15 valsartan --</p> <p>16 MR. HARKINS:</p> <p>17 Object to form. You can answer.</p> <p>18 MS. BOGDAN:</p> <p>19 Q -- when --</p> <p>20 A I believe so.</p> <p>21 Q And did you --</p> <p>22 A I looked at a variety -- I looked at a</p> <p>23 variety of methods that a variety of people</p> <p>24 published, and I believe NDMA is one of -- FDA is</p>
<p>Page 171</p> <p>1 had ZHP results, Mylan results, and Teva results,</p> <p>2 and it's hard for me to keep that perfectly</p> <p>3 straight as -- in my head. But, yes, I believe</p> <p>4 I've reviewed this data.</p> <p>5 Q And the results that you reviewed with</p> <p>6 regard to testing of the Mylan API batches, did</p> <p>7 those results show API batches that were found to</p> <p>8 have NDEA values above the provisional limit of</p> <p>9 0.08 parts per million?</p> <p>10 A As I -- as I recall, yes, to the best</p> <p>11 of my recollection.</p> <p>12 MS. BOGDAN:</p> <p>13 Will you please pull up exhibit --</p> <p>14 I believe it's number 21 in the</p> <p>15 document repository, but...</p> <p>16 (DEPOSITION EXHIBIT NUMBER 15</p> <p>17 WAS MARKED FOR IDENTIFICATION.)</p> <p>18 MS. BOGDAN:</p> <p>19 Q Are you aware, Dr. Baertschi, of the</p> <p>20 testing methods that the FDA published for</p> <p>21 determining levels of NDEA or NDMA in valsartan?</p> <p>22 A I -- I have seen a number of</p> <p>23 publications talking about post-July -- you know,</p> <p>24 2019 and 2020 and 2021, even, where a variety of</p>	<p>Page 173</p> <p>1 one of them, and I believe I've reviewed those.</p> <p>2 Q Did you compare those testing methods</p> <p>3 that the NDMA -- that the FDA published for NDMA</p> <p>4 and NDEA and inquire whether Teva had those</p> <p>5 testing capabilities?</p> <p>6 A It was never a question in my mind</p> <p>7 whether or not Teva would have the testing</p> <p>8 capabilities.</p> <p>9 And let me define testing capabilities.</p> <p>10 By having the instrumentation and even the -- the</p> <p>11 expertise to be able to carry out such a method</p> <p>12 or protocol. So I don't know for sure, but I --</p> <p>13 my presumption is that they would.</p> <p>14 Q And when you say there was never a</p> <p>15 question in your mind whether Teva would have the</p> <p>16 testing capabilities, why wasn't there a question</p> <p>17 in your mind?</p> <p>18 A Because I don't think that the --</p> <p>19 The instrumentation and expertise is</p> <p>20 outside of the norm of a pharmaceutical company</p> <p>21 to have within its -- within its company or</p> <p>22 within -- within -- accessible from a contract</p> <p>23 lab or something.</p> <p>24 The -- the technology itself is not</p>

<p>Page 174</p> <p>1 something that I would be concerned about a 2 typical large company like Teva having access to. 3 MS. BOGDAN: 4 If we could pull up Exhibit 21. Or, 5 actually, I should ask, before you pull that up, 6 Steve, I see we're hitting on 1:30. 7 MR. HARKINS: 8 Yeah. Our lunch is here. 9 Dr. Baertschi, it's up to you. 10 THE WITNESS: 11 Yeah. So let's take a break and eat. 12 MS. BOGDAN: 13 Okay. That's fine. I just wanted to 14 acknowledge that we had reached that time, and I 15 don't -- I don't know if anyone got anything hot, 16 but I wouldn't want the soup to get cold on my 17 account. So do you want to take a -- just, like, 18 can we keep it to about 30 minutes? 19 MR. HARKINS: 20 So let us -- let me check back in in 30 21 minutes. We might need a few more than that. 22 But I'll jump back on at 2:00 and let you guys 23 know how long we'll need. 24 MS. BOGDAN:</p>	<p>Page 176</p> <p>1 valsartan. Have you reviewed these methods that 2 the FDA published? 3 A Yes. I've seen these. 4 Q Okay. With regard to this first 5 method, it says "by GC/MS-Headspace." 6 A Yes. 7 Q Could you tell us what GC/MS-Headspace 8 is? 9 A Yeah. It's a -- it's a hyphenated 10 technique starting with -- the separation occurs 11 in gas -- a gas chromatographic separation using 12 heat to -- to volatilize constituents, and then 13 they go through a column and separate it out 14 based on their vapor pressure and their 15 attraction to the stationary phase on the column, 16 the capillary column, and then they are eluted 17 into a mass spectrometer which detects on the 18 basis of molecular weight. 19 The Headspace part is where you have a 20 sample in a vial, typically, with a solution, and 21 you heat the solution, and it drives off volatile 22 constituents into equilibrium in the headspace, 23 and then you're just sampling the Headspace gas 24 and injecting that headspace gas onto the gas</p>
<p>Page 175</p> <p>1 Okay. I'm just trying to make sure 2 we're not here -- okay. 3 MR. HARKINS: 4 Can we go off the record? 5 MS. BOGDAN: 6 Yes. 7 VIDEOGRAPHER: 8 Off the record. 1:29 p.m. 9 (LUNCH RECESS) 10 VIDEOGRAPHER: 11 On record, 2:21 p.m. 12 MS. BOGDAN: 13 Could you please mark what I believe is 14 in the repository as number 21? 15 MS. BOGDAN: 16 Which are my -- marked, I think, 17 Combined Headspace Method. 18 Q Okay, Doctor. And let me know once 19 you're able to see that. It should be coming up 20 as an FDA document. 21 A I can see it. 22 Q Okay. And, for the record, this 23 exhibit is several publications from the FDA with 24 regard to methods for testing NDMA and NDEA in</p>	<p>Page 177</p> <p>1 chromatograph to separate and then eventually 2 detect. 3 Q And how long has gas chromatography 4 been around? 5 A I could not tell you the very 6 beginning, but '50s or '60 -- 1950s or '60s, 7 maybe before that, '40s, '30s, a long time. But 8 the technology has changed dramatically over the 9 years. 10 Q So the technology has changed over the 11 years, but gas chromatography was first available 12 50 years or so or more ago? 13 A At least that long ago, yes, I believe. 14 Q And what about mass spectrometry? How 15 long has that been around? 16 A That's kind of a loaded question, 17 because some forms of mass spectrometry may have 18 been around for 50, 60, 70, 80 years. I'm not 19 even sure. I used to know that number years ago 20 when I was in graduate school, maybe. But mass 21 spectrometers have continued to evolve over the 22 years and -- and get much more resolution and 23 capability and sensitivity. But they've been 24 around for a long time as a technology or</p>

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1 instrument.

2 Q If we could go to what I believe is

3 page 8, maybe, of the exhibit.

4 A I'm only seeing six pages, but...

5 Q Oh, okay. They're -- I think that we

6 need to maybe pull up the next exhibit, which is

7 number 22 in the repository, which is entitled

8 "Combined Direct Injection." Do you see that?

9 A I've got it.

10 MS. BOGDAN:

11 What exhibit is this, so we don't lose

12 track?

13 TRIAL TECH:

14 Sixteen.

15 MR. HARKINS:

16 That's for the court reporter.

17 (DEPOSITION EXHIBIT NUMBER 16

18 WAS MARKED FOR IDENTIFICATION.)

19 MS. BOGDAN:

20 Q Now, is this testing method another one

21 that is by GC/MS?

22 A Yes. Says so in the title, by GC/MS.

23 Q And this one does not have the

24 Headspace designation.

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1 A Yeah. It doesn't say that in the

2 designation. I haven't looked through the method

3 to make sure that it's not using Headspace.

4 Q And is this testing method also using

5 gas chromatography and mass spectrometry?

6 A Yes.

7 Q Gas chromatography is the type of

8 instrument that you would expect most

9 pharmaceutical companies to have?

10 A Yes.

11 Q And mass spectrometry is an instrument

12 that you would expect most pharmaceutical

13 companies to have?

14 A Yeah, I would expect most

15 pharmaceutical companies to have a mass

16 spectrometer in their -- in their company.

17 Q Do you recall --

18 A Not all --

19 Okay. Sorry.

20 Q I'm sorry.

21 Did you familiarize yourself with all

22 of the testing methods that the FDA has published

23 as appropriate for testing for NDMA or NDEA in

24 valsartan products?

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1 MR. HARKINS:

2 Object to form. Vague.

3 A I didn't spend a lot of time trying to

4 verify whether or not the -- the methods were

5 valid. I would presume, based on the FDA, the

6 reputation of the -- of the -- the focus that

7 this topic has had, that they would have done a

8 very thorough job, and I would believe them, by

9 default, to have put out a method. So there was

10 no question in my mind that I needed to review it

11 for validity.

12 MS. BOGDAN:

13 Q I wasn't asking if you -- that wasn't

14 what I was trying to get to when I asked the

15 question, so I apologize.

16 What I was asking is simply if you did

17 familiarize yourself with the various testing

18 methods that were set forth by the FDA for

19 measuring NDMA or NDEA in valsartan.

20 A I believe I answered that before in

21 that I looked at a lot of the methods that have

22 come out from FDA and other regulatory agencies

23 as well as private companies. I'm not -- I have

24 not -- when you say have you familiarized

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1 yourself, I've looked at a lot of the different

2 methods. I can't say that I would be ready for a

3 quiz if we were taking a quiz.

4 Q Did you question the validity of any of

5 the methods that the FDA put forth for the ones

6 you reviewed?

7 A I have -- for valsartan, no.

8 MS. BOGDAN:

9 All right. If we could pull up the

10 5-21-2019 FDA method, which is document 26, I

11 believe, in the repository. Please mark that as

12 an exhibit.

13 (DEPOSITION EXHIBIT NUMBER 17

14 WAS MARKED FOR IDENTIFICATION.)

15 MS. BOGDAN:

16 Q Doctor, let me know when you can see

17 that on your screen.

18 A I can see it on my screen.

19 Q Okay. This testing method refers to

20 LC-HRMS; correct?

21 A Correct.

22 Q How does that differ from GC/MS?

23 A Yes, it is distinct from GC/MS.

24 Q And how does it differ?

<p style="text-align: right;">Page 182</p> <p>1 A LCMS -- HP -- LCMS is -- HPLC-MS. So</p> <p>2 we've already talked about HPLC and how it works.</p> <p>3 It's just instead of taking the eluent off the</p> <p>4 detect- -- off the column into a UV detector,</p> <p>5 you're taking it and going into a mass</p> <p>6 spectrometer of some sort. In this case, it's a</p> <p>7 particular type of mass spectrometer that is high</p> <p>8 resolution.</p> <p>9 Q Okay.</p> <p>10 A And that's significant.</p> <p>11 Q All right. So this particular testing</p> <p>12 method has HPLC on the front end?</p> <p>13 A Right.</p> <p>14 Q Okay. And, then, it's using a high</p> <p>15 resolution mass spec on the back end?</p> <p>16 A Yes.</p> <p>17 Q And is the -- the LC in this method, is</p> <p>18 that the same type of instrument that would be</p> <p>19 used for HPLC impurity testing?</p> <p>20 A Yes.</p> <p>21 Q And, then, the mass spectrometry that's</p> <p>22 being used, is that somehow different from the</p> <p>23 mass spectrometry that's noted in the GC/MS</p> <p>24 testing methods that we just looked at, which</p>	<p style="text-align: right;">Page 184</p> <p>1 formula.</p> <p>2 Q And when was that technology invented?</p> <p>3 A That -- well, the invention of it, the</p> <p>4 Q exactive -- I'm not exactly sure, but that's</p> <p>5 probably within the last --</p> <p>6 Combined with the Orbitrap, I don't</p> <p>7 know. It's five or ten years, I would guess.</p> <p>8 I'm not exactly sure. I'm not an instrument --</p> <p>9 You know, instrument vendors would --</p> <p>10 Thermo Fisher could tell you. I'm not exact</p> <p>11 sure. But it certainly wasn't around 20 or 30</p> <p>12 years ago.</p> <p>13 MS. BOGDAN:</p> <p>14 And if we could please pull up as and</p> <p>15 mark as an exhibit the July 24th, 2019,</p> <p>16 RapidFire-MS/MS method.</p> <p>17 (DEPOSITION EXHIBIT NUMBER 18</p> <p>18 WAS MARKED FOR IDENTIFICATION.)</p> <p>19 MS. BOGDAN:</p> <p>20 Q Dr. Baertschi, I can see it, but let me</p> <p>21 know when you can, please.</p> <p>22 A I have it now up.</p> <p>23 Q You see on that exhibit that it talks</p> <p>24 about development and validation of a</p>
<p style="text-align: right;">Page 183</p> <p>1 were alternative FDA methods for testing NDMA and</p> <p>2 NDEA in valsartan?</p> <p>3 A Yes, very significantly different.</p> <p>4 Q Okay. How is HRMS different?</p> <p>5 A Well, if -- if you look in the</p> <p>6 equipment instrument part --</p> <p>7 I don't know what page that is. Looks</p> <p>8 like it's 2 of 12.</p> <p>9 -- they describe the LC equipment --</p> <p>10 the MS equipment. And this is a very kind of</p> <p>11 state-of-the-art -- not kind of. It is a</p> <p>12 state-of-the-art piece of equipment. It has two</p> <p>13 mass spec sectors on it. One's a quadripole,</p> <p>14 which is nominal mass resolution, which means one</p> <p>15 atomic mass unit resolution, and then it's</p> <p>16 combined with an Orbitrap mass spectrometer,</p> <p>17 which is like ion cyclotron resonance mass</p> <p>18 spectrometry, which -- I won't try to explain it.</p> <p>19 But it is -- it is more of a state of the art</p> <p>20 that allows you to measure very high resolution,</p> <p>21 not just one AMU, but you can go to tenths and</p> <p>22 thousandths of an AMU and distinguish between</p> <p>23 isomers or topoisomers, compounds that have same</p> <p>24 molecular weight but a different molecular</p>	<p style="text-align: right;">Page 185</p> <p>1 RapidFire-MS/MS method?</p> <p>2 A Yes, I do.</p> <p>3 MS. BOGDAN:</p> <p>4 God bless you.</p> <p>5 MS. LANGTON:</p> <p>6 Thank you.</p> <p>7 MS. BOGDAN:</p> <p>8 God bless you.</p> <p>9 MS. LANGTON:</p> <p>10 Thank you.</p> <p>11 MS. BOGDAN:</p> <p>12 Q Are you familiar with a RapidFire-MS/MS</p> <p>13 method?</p> <p>14 A I have heard the terminology, and I --</p> <p>15 it's new enough that I haven't -- well, I don't</p> <p>16 know if it's new enough. I am not exactly sure.</p> <p>17 It's a trademark. And I can kind of figure it</p> <p>18 out from looking what's in this document, but I'm</p> <p>19 not, like, intimately familiar with RapidFire</p> <p>20 technology.</p> <p>21 Q Would you consider yourself an expert</p> <p>22 on RapidFire-MS/MS technology?</p> <p>23 A No.</p> <p>24 MR. HARKINS:</p>

<p style="text-align: right;">Page 186</p> <p>1 Object to form to the extent it calls</p> <p>2 for a legal conclusion.</p> <p>3 A I do -- I do not have experience with</p> <p>4 RapidFire. I've seen publications talking about</p> <p>5 it, but I have not studied it.</p> <p>6 MS. BOGDAN:</p> <p>7 Q With regard to the LC-HRMS method that</p> <p>8 we just spoke about with the previous exhibit,</p> <p>9 have you ever run a test like that yourself?</p> <p>10 A For -- have I ever run a test like that</p> <p>11 for nitrosamines?</p> <p>12 Q Or for anything. An LC HRMS.</p> <p>13 A Yes, but -- yes, I have, with</p> <p>14 assistance.</p> <p>15 Q And when you say "with assistance,"</p> <p>16 what do you mean?</p> <p>17 A To -- to getting the setup --</p> <p>18 Oftentimes in industry you'll have a</p> <p>19 mass spec instrumentation guide that will set up</p> <p>20 a variety of instruments for open access for --</p> <p>21 to allow other people to come and use. And, so,</p> <p>22 as a user, you don't have to set up all the</p> <p>23 parameters to -- to exacting precision. It's</p> <p>24 already been done for you. So it's kind of, from</p>	<p style="text-align: right;">Page 188</p> <p>1 type of test before?</p> <p>2 A Yes.</p> <p>3 Q And did you need the assistance of a</p> <p>4 instrumentation specialist to run that test, or</p> <p>5 is that something that you were capable, as the</p> <p>6 instrument operator, of running without</p> <p>7 assistance?</p> <p>8 A I used to do GC/MS routinely every day</p> <p>9 from about 1981 through 1986 or so, and then</p> <p>10 occasionally in the early '90s. I have not</p> <p>11 personally operated a GC/MS since probably</p> <p>12 mid-1990s.</p> <p>13 Q When you operated GC/MS in the 1980s,</p> <p>14 that was in your capacity of working for Eli</p> <p>15 Lilly?</p> <p>16 A That was a previous position that I had</p> <p>17 before graduate school.</p> <p>18 Q What position was that?</p> <p>19 A I think the technical term that I --</p> <p>20 the title was Residues Chemist. I worked at --</p> <p>21 in an environmental analysis laboratory.</p> <p>22 Q Okay. And what type of --</p> <p>23 Was it GC/MS that you were using?</p> <p>24 A Yes.</p>
<p style="text-align: right;">Page 187</p> <p>1 a user point of view, it's easier.</p> <p>2 Q And, so, you were the instrument</p> <p>3 operator, but the instrument was already</p> <p>4 programmed?</p> <p>5 MR. HARKINS:</p> <p>6 Object to form. Vague.</p> <p>7 MS. BOGDAN:</p> <p>8 Q I'm just trying to understand what</p> <p>9 you're explaining.</p> <p>10 A I was the instrument -- instrument</p> <p>11 operator, yes, but I'm not an instrumentation</p> <p>12 specialist. And it is common to have a</p> <p>13 specialist set up instruments to allow other</p> <p>14 chemists to use who only come in and use them</p> <p>15 once in a while and are --</p> <p>16 To save them time from having to set up</p> <p>17 everything themselves, they -- they get</p> <p>18 assistance with the person who's responsible for</p> <p>19 the setup.</p> <p>20 I'm not sure if that's vague or not,</p> <p>21 but it's honest.</p> <p>22 Q No. I -- I understand your -- your</p> <p>23 response. Thank you.</p> <p>24 With regard to GC/MS, have you run that</p>	<p style="text-align: right;">Page 189</p> <p>1 Q What type of machine? Do you remember?</p> <p>2 A It was a Hewlett Packard. Uh-huh. It</p> <p>3 was a quadripole detector, nominal mass. Would</p> <p>4 not have the kind of sensitivity you'd need to be</p> <p>5 able to carry out the N-nitrosamine analysis that</p> <p>6 we're talking about now. Quite a -- quite a</p> <p>7 number of years ago.</p> <p>8 Q Did you review the warning letters</p> <p>9 issued by the FDA to ZHP and Mylan concerning</p> <p>10 their valsartan API?</p> <p>11 A It depends on what you mean by review.</p> <p>12 I've -- I've seen them. I -- I don't -- I can't</p> <p>13 pull them up in my brain as we talk. I'd be</p> <p>14 happy to look at them if you want me to.</p> <p>15 MS. BOGDAN:</p> <p>16 If we could please pull up ZHP warning</p> <p>17 letter, November 29th, 2018.</p> <p>18 (DEPOSITION EXHIBIT NUMBER 19</p> <p>19 WAS MARKED FOR IDENTIFICATION.)</p> <p>20 MS. BOGDAN:</p> <p>21 And please mark it as an exhibit.</p> <p>22 What exhibit number are we on?</p> <p>23 THE COURT REPORTER:</p> <p>24 Nineteen.</p>

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1 TRIAL TECH:
2 Nineteen.
3 THE COURT REPORTER:
4 I'm sorry. It's 19.
5 MS. BOGDAN:
6 Q It's document 31 in the repository.
7 A Yes, I see it. I have it.
8 Q Okay. Did you review this warning
9 letter as part of your investigation into this
10 case?
11 A Yes. I do -- I do remember this.
12 Q And directing your attention to page 2
13 of the warning letter --
14 Well, first of all, let's just -- this
15 was November 29th, 2018; correct?
16 A Yes.
17 Q All right. And this warning letter is
18 directed to ZHP --
19 A Yes.
20 Q -- over in China.
21 A Right. Yes.
22 Q Correct?
23 And it's directed to a Mr. Du, D-U;
24 correct?

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1 A Yes.
2 Q Then, on the bottom of this page, it's
3 referring to valsartan API; correct?
4 A Yes.
5 Q And then on page 2 of this letter --
6 Oops. I'm sorry. I think you have to
7 go back to page 1. Thank you.
8 The third paragraph down --
9 A Yes.
10 Q -- where it says "because of your
11 methods" --
12 A Okay. I see that.
13 Q -- "facilities" --
14 Okay. All right. Could you read that
15 sentence, please.
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 Q And during your research and
23 investigation into this case, did you learn any
24 information that contradicts what's in that

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1 statement in this letter from the FDA to Mr. Du?
2 MR. HARKINS:
3 Object to form. Outside the scope of
4 his expert opinion and calls for a legal
5 conclusion. Vague.
6 A Yes, I -- I don't quite know. Could
7 you restate the question?
8 MS. BOGDAN:
9 Q Did you learn, during the course of
10 your investigation into this case, any
11 information that would cause you to disagree with
12 that sentence?
13 MR. HARKINS:
14 Same objection. Form. Scope. Calls
15 for a legal conclusion. Vague.
16 A Yeah. I -- I don't know how to define
17 adulterated and -- and how --
18 That's a -- sort of a regulatory term,
19 FDA term, and I've not -- I've not studied that
20 term in what qualifies as adulterated. It's not
21 part of my investigation.
22 MS. BOGDAN:
23 Q So you're not offering, then, any
24 opinions in this case regarding product being

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1 adulterated or not adulterated?
2 A I -- to my knowledge, yeah, I've not
3 been asked to look at the term "adulterated" or
4 "not adulterated" for my expert report.
5 Q So you are not offering any opinions in
6 this matter with regard to adulteration; correct?
7 MR. HARKINS:
8 Objection. Just qualify it to the
9 extent, "this matter." He's not offering any
10 opinions about them in this report submitted for
11 the class certification phase of this case.
12 You can answer.
13 A To date, I haven't offered, I don't
14 think, any -- any opinion on adulteration, of
15 that term, on how that term plays into this case.
16 MS. BOGDAN:
17 Q Are you --
18 Okay. Are you offering any opinions
19 regarding the value of the drug product
20 manufactured by Teva Pharmaceutical that was
21 recalled?
22 A Do you mean commercial value? What
23 does value mean?
24 Q I mean -- I mean commercial value.

<p style="text-align: right;">Page 194</p> <p>1 A I'm not offering any opinion on a 2 commercial value. 3 Q Are you offering any opinions regarding 4 any other values of the Teva drug product? 5 MR. HARKINS: 6 Object to form. Vague. Outside the 7 scope. 8 You can answer if you can. 9 A I am not offering -- I don't -- I don't 10 think I am offering an opinion as you described 11 it, and I've kind of forgotten what -- what it is 12 that -- 13 You probably need to restate the 14 question for me. 15 MS. BOGDAN: 16 Q I had asked you a question if you were 17 offering any opinions regarding the value of the 18 Teva drug products. And when I meant value, I 19 meant monetary value. And, so, and you said 20 values, what values? So I'm just trying to 21 circle back with regard to that question and ask 22 if you're offering any opinions with regard to 23 the monetary value of the Teva drug products. 24 A I am not offering any opinion related</p>	<p style="text-align: right;">Page 196</p> <p>1 A Sorry. 2 Q So were you familiar with this ICH 3 guideline as it went through its various 4 revisions? 5 A Yes. 6 Q And what is ICH? 7 A ICH is the International Conference on 8 Harmonization. 9 Q And what purpose does it serve? 10 A It was originally put together to try 11 to harmonize Europe, what was then EMEA, FDA, and 12 Japan so that there was one set of consistent 13 guidances that could be used for regulatory 14 submissions instead of separate ones for each 15 region. And, so, it was a tripartite harmonized 16 guidance. That was the intent, as I recall. 17 Q And just so that everyone understands, 18 you're talking about in the pharmaceutical 19 industry or -- or something else? 20 A Pharmaceutical industry. So for INDs, 21 ANDAs -- well, and NDAs. Pharmaceutical 22 products. 23 Q And this particular guideline deals 24 with impurities; correct?</p>
<p style="text-align: right;">Page 195</p> <p>1 to the value of the valsartan drug products or 2 the Teva drug products, however you want to 3 characterize them. 4 MS. BOGDAN: 5 Could we please pull up the ICH Q3 6 guidance, which I believe is number 34? 7 (DEPOSITION EXHIBIT NUMBER 20 8 WAS MARKED FOR IDENTIFICATION.) 9 A I've got it up. 10 MS. BOGDAN: 11 Q Okay. Now, are you familiar with this 12 ICH guidance? 13 A Yes, I am. 14 Q And what date is this guidance, or what 15 date was it issued? 16 A Well, the -- the revision 2 was issued 17 on October 25th, 2006, as it says there. There 18 were previous -- there was an R1 and there was 19 a -- before, there was an R1, and I believe the 20 Q3 goes back to 1993, if I'm remembering 21 correctly off the top of my head. 22 Q If we look at the second page of this 23 guideline, I think it gives a little bit of 24 information regarding the history.</p>	<p style="text-align: right;">Page 197</p> <p>1 A Correct. Impurities -- 2 Q And what is -- 3 A Go ahead. 4 Q What is an impurity? 5 A Well, there's a definition. Can we go 6 to the back of this? It defines impurity. I 7 could vaguely describe it, but it will be a more 8 precise description if we go to the -- to the 9 back of this document and look at the -- 10 Q Sure. I believe the glossary starts on 11 page 6 -- 12 A Yeah. 13 Q -- if that's accessible to you, and 14 goes to page 7. 15 A I'm on page -- yes, on 7. 16 An impurity -- I can read it. "An 17 impurity is any component of the new -- component 18 of the new drug substance that is not a chemical 19 entity defined as the new drug substance." 20 Q Do you agree with that definition? 21 A Yes. 22 Q And what does that mean, in layperson's 23 terms? 24 A In layperson's terms, it would be a</p>

<p style="text-align: right;">Page 198</p> <p>1 variety of ways to think of it. But if you think 2 of a glass of water and there's just a little bit 3 of blue dye in it, you know, you can -- you 4 can -- it's something that's not supposed -- you 5 can see it, you can visually see that there's 6 something in there, even though it might be at a 7 very minuscule level, so it's something that's 8 not part of the -- it's not water. It's 9 something else.</p> <p>10 So in this case, it's not the drug 11 substance. It's not the API. It's something 12 apart from the API that is in the API.</p> <p>13 Q And when you use the term "API," can 14 you define that?</p> <p>15 A Active pharmaceutical ingredient. So 16 sometimes API and drug substance term is used 17 interchangeably. There are some conventions that 18 discriminate how to use it, but typical jargon in 19 the pharmaceutical industry is to use them 20 interchangeably.</p> <p>21 Q So an impurity is something that's in 22 the active pharmaceutical ingredient that is not 23 the actual active pharmaceutical ingredient.</p> <p>24 A Yeah. And maybe it's clearer to say an</p>	<p style="text-align: right;">Page 200</p> <p>1 we're looking at is the 2006 version; correct? 2 But there were versions of this in 2002 as well?</p> <p>3 A Yes.</p> <p>4 Q Okay. And if we go to page 1, which is 5 the next page after document history --</p> <p>6 MS. BOGDAN:</p> <p>7 One more page, please. I'm sorry. Two 8 pages after document history. It starts 9 "impurities in new drug substances." There we 10 go.</p> <p>11 Q Do you see how it, under subsection 2, 12 it has classification of impurities?</p> <p>13 A Yes.</p> <p>14 Q It classifies impurities into three 15 different categories?</p> <p>16 A Yes.</p> <p>17 Pardon me, my throat. Hold on a 18 second.</p> <p>19 MR. HARKINS:</p> <p>20 Would you like a glass of water or 21 something?</p> <p>22 THE WITNESS:</p> <p>23 Yeah, maybe so.</p> <p>24 MS. LANGTON:</p>
<p style="text-align: right;">Page 199</p> <p>1 impurity is something in the drug substance which 2 is -- that is not the active pharmaceutical 3 ingredient.</p> <p>4 Q Now, in that glossary section, it also 5 has a definition for potential impurity. Do you 6 see that? It's -- I believe they're in 7 alphabetical order.</p> <p>8 A I do see it.</p> <p>9 Q What is the definition of potential 10 impurity?</p> <p>11 A An impurity that theoretically can 12 arise during manufacture or storage. It may or 13 may not actually appear in the new drug 14 substance.</p> <p>15 Q Do you agree with that definition of 16 potential impurity?</p> <p>17 A Yes. There's -- the only sticking 18 point is theoretical versus potential. And I 19 think, from a practical point of view, it's a 20 fine definition. It may get revised in the next 21 version of -- revision of ICH Q3A, but it's a 22 fine working definition.</p> <p>23 Q All right. If we could go back to page 24 1 of the guidance. And this version of it that</p>	<p style="text-align: right;">Page 201</p> <p>1 I'll get one.</p> <p>2 A Yes. Pardon me. Now my voice --</p> <p>3 But I see the three classifications, 4 organic, inorganic, and residual solvents.</p> <p>5 MS. BOGDAN:</p> <p>6 Q Okay. Do you agree that impurities can 7 be classified into those three categories?</p> <p>8 A Yes.</p> <p>9 Q And the NDMA and NDEA that was found in 10 valsartan-containing drugs, which type of 11 impurity category would they fall under?</p> <p>12 A Organic impurities.</p> <p>13 Q And the guidance goes on to explain how 14 organic impurities can arise?</p> <p>15 A Yes.</p> <p>16 Q And what does the guidance tell us 17 about how organic impurities can arise?</p> <p>18 A They can arise during the manufacturing 19 process and/or storage of the new drug substance.</p> <p>20 Q And do you agree with that?</p> <p>21 A Yes.</p> <p>22 Q Then the guideline goes on to tell us 23 that the organic impurities can be identified or 24 unidentified, volatile or nonvolatile.</p>

<p style="text-align: right;">Page 202</p> <p>1 Do you agree with that?</p> <p>2 A Yes, I -- I agree with that.</p> <p>3 Q And it tells us that the organic</p> <p>4 impurities -- it reads "they can be identified or</p> <p>5 unidentified, volatile or nonvolatile, and</p> <p>6 include starting materials, byproducts,</p> <p>7 intermediates, degradation products, reagents,</p> <p>8 ligands, and catalysts."</p> <p>9 Do you see that?</p> <p>10 A I do see that.</p> <p>11 Q Do you agree with that statement in the</p> <p>12 guideline?</p> <p>13 A Yes, I agree with that statement.</p> <p>14 Q And when evaluating a manufacturing</p> <p>15 process as a chemist, should one be looking for</p> <p>16 potential impurities that can form?</p> <p>17 MR. HARKINS:</p> <p>18 Object to form. Calls for speculation.</p> <p>19 Vague.</p> <p>20 A Should --</p> <p>21 So I'm gonna restate the question as</p> <p>22 best I answer it. Should -- when you're</p> <p>23 developing a synthetic process, should one be</p> <p>24 looking for potential impurities that could form</p>	<p style="text-align: right;">Page 204</p> <p>1 sound scientific appraisal of the chemical</p> <p>2 reactions involved in the synthesis, impurities</p> <p>3 associated with raw materials that could</p> <p>4 contribute to the impurity profile of the new</p> <p>5 drug substance, and possible degradation</p> <p>6 products."</p> <p>7 Q Do you agree with that statement?</p> <p>8 A Yeah. It's all part of the guidance,</p> <p>9 so, in a way, it doesn't matter if I agree with</p> <p>10 it or not. It is what it is. But I have no</p> <p>11 problem with the wording of this -- what -- of</p> <p>12 what we've highlighted.</p> <p>13 Q As an expert organic chemist that has</p> <p>14 worked in the pharmaceutical industry, do you</p> <p>15 agree that it's good practice to follow the</p> <p>16 guidance, and the applicant should summarize the</p> <p>17 actual and potential impurities most likely to</p> <p>18 arise during the synthesis, purification, and</p> <p>19 storage of the new drug substance?</p> <p>20 A Yes. I agree that that's good</p> <p>21 practice.</p> <p>22 Q And do you agree that it's good</p> <p>23 practice that the summary should be based on</p> <p>24 sound scientific appraisal of the chemical</p>
<p style="text-align: right;">Page 203</p> <p>1 in the synthetic process? I would say yes.</p> <p>2 Q Now, if we go to the next page of the</p> <p>3 ICH guideline, under rationale for the reporting</p> <p>4 and control of impurities, it has a section for</p> <p>5 organic impurities; correct?</p> <p>6 A Yes. Agree.</p> <p>7 Q NDMA and NDEA would be organic</p> <p>8 impurities.</p> <p>9 A Yes. Agreed.</p> <p>10 Q What does the first sentence say under</p> <p>11 that section?</p> <p>12 A "The applicant should summarize the</p> <p>13 actual and potential impurities most likely to</p> <p>14 arise during the synthesis, purification, and</p> <p>15 storage of the new drug substance."</p> <p>16 Q ...that statement?</p> <p>17 A Do -- could you repeat? Something cut</p> <p>18 out.</p> <p>19 Q Sorry. Do you agree with that</p> <p>20 statement?</p> <p>21 A Yes, I do.</p> <p>22 Q Okay. Then if you could read the next</p> <p>23 sentence, please.</p> <p>24 A "This summary should be based upon</p>	<p style="text-align: right;">Page 205</p> <p>1 reactions involved in the synthesis, impurities</p> <p>2 associated with raw materials that contribute to</p> <p>3 the impurity profile of the new drug substance,</p> <p>4 and possible degradation products?</p> <p>5 MR. HARKINS:</p> <p>6 Object to form as to the extent good</p> <p>7 practice means anything different than following</p> <p>8 the guidance.</p> <p>9 You can answer.</p> <p>10 A Yeah, there's -- there doesn't seem to</p> <p>11 be anything controversial there. I think it's</p> <p>12 clear. And I -- I have no -- I take no issues</p> <p>13 with the wording.</p> <p>14 MS. BOGDAN:</p> <p>15 Q If we could go down to the last</p> <p>16 paragraph in that section, which reads</p> <p>17 "identification of impurities present at an</p> <p>18 apparent level of not more than, less than, or</p> <p>19 greater or equal to the identification threshold</p> <p>20 is generally not considered necessary."</p> <p>21 And then it goes on to say, "However,</p> <p>22 analytical procedures should be developed for</p> <p>23 these -- those potential impurities that are</p> <p>24 expected to be unusually potent, producing toxic</p>

<p style="text-align: right;">Page 206</p> <p>1 or pharmacological effects at a level not more 2 than the identification threshold." 3 Are you familiar with that language? 4 A I am familiar with that language. 5 Q What is it referring to when it says 6 analytical procedures should be developed for 7 those potential impurities that are expected to 8 be unusually potent? 9 A It was undefined at the time of ICH 10 Q3A, and other revisions remain undefined. But 11 it has been discussed in numerous literature 12 articles, including some of my own, that that was 13 generally believed to be a placeholder for, at 14 the time, genotoxic impurities and, later, as 15 that was refined, mutagenic impurities. 16 But it would not be limited to, because 17 there could be other toxic -- you could have 18 something that causes convulsions or something 19 that causes some other form of -- of toxic event. 20 So it's not limited to, but it was intended to 21 include mutagenic impurities. 22 Q And, so, it was intended to include 23 mutagenic impurities such as NDMA and NDEA? 24 A Yes. They would be examples of</p>	<p style="text-align: right;">Page 208</p> <p>1 A Yes. 2 Q All right. And, then, the analytical 3 procedure, aside from separating and detecting, 4 can also be developed to actually quantify the 5 amount of the material; correct? 6 A Yes. Yes. That's the implication. 7 There are exceptions to that in terms of 8 quantification. Sometimes there are limit tests. 9 So -- and there are limit tests that could be 10 applicable to certain mutagenic impurity, you 11 know, below or above, pass/fail. But, in 12 general, the way you stated it, I would agree 13 with. 14 Q Now, moving to page 8 of the guidance, 15 which has Attachment 1, Thresholds, and a chart, 16 do you see that? 17 A Yes, I do. 18 Q Okay. And it has different headings on 19 this chart for maximum daily dose, which I assume 20 would be the amount of the medication one would 21 be taking in a day; correct? 22 A Correct. 23 Q And then it has column headings. One 24 is reporting threshold. What is meant by a</p>
<p style="text-align: right;">Page 207</p> <p>1 mutagenic impurities that would be -- yes. 2 Q And when it references analytical 3 procedures that should be developed, would those 4 be analytical methods to test for those potential 5 impurities? 6 A Yeah. It would be analytical 7 procedures to separate, detect, and quantify, as 8 appropriate, those potential impurities. 9 So when you say test, it's a little 10 vague, so I was providing my understanding of the 11 intention is to have -- to separate, detect, and 12 potentially quantify. 13 Q You say "to separate." That would mean 14 to separate them from the active pharmaceutical 15 ingredient; correct? 16 A Typically, yes. There are ways to 17 sep- -- 18 Yes, that's the implication. There are 19 ways to "and devise analytical measures" to where 20 you don't actually separate. So your -- your 21 signal, your detection signal would need to be 22 separate and unique to the impurity of interest. 23 Q Procedures should be developed to 24 detect the impurity.</p>	<p style="text-align: right;">Page 209</p> <p>1 reporting threshold? 2 A It -- it means that if you integrate 3 a -- a -- an impurity below .05 percent, you 4 don't have to integrate and report the presence 5 of that impurity. To report it -- 6 You can, but they're -- they're leaving 7 an expectation -- they're showing an expectation 8 here that if it's .05 percent or above, then you 9 should report it. 10 Q To what -- 11 A By report, it means integrate it, put 12 it in your -- in your records and put it in a 13 regulatory document or wherever -- whatever phase 14 of development is appropriate for the 15 regulatory -- regulatory recording requirements. 16 Q And then there's a separate column for 17 identification threshold. What is meant by an 18 identification threshold? 19 A It means to -- to identify it 20 structurally so that you can identify the 21 chemical molecular structure of the -- of the 22 impurity. 23 Q Okay. And, then, qualification 24 threshold, what is meant by that?</p>

<p style="text-align: right;">Page 210</p> <p>1 A That means that you have --</p> <p>2 qualification is a toxicological safety</p> <p>3 terminology, so that means you qualified it as</p> <p>4 safe through some series of toxicology test at</p> <p>5 that level.</p> <p>6 So if something is present, a -- a</p> <p>7 compound is present at .15 percent or 1 milligram</p> <p>8 per day or above, then you need to have some --</p> <p>9 If it's below, you don't have to do any</p> <p>10 special qualification, any special toxicology</p> <p>11 studies. If it's above, then you would have to</p> <p>12 do some kind -- there's certain specified testing</p> <p>13 to show the safety at that level.</p> <p>14 Q Now, if we could move to page 11 of</p> <p>15 this guideline, and directing you to the notes on</p> <p>16 attachment 3 section. And the attachment 3,</p> <p>17 Dr. Baertschi, is on the page before, just so</p> <p>18 that you have the ability to get to it if you</p> <p>19 want to review it.</p> <p>20 A Yeah. I can see it.</p> <p>21 Q You can see it? Okay.</p> <p>22 A Well, I mean, I have the document, so</p> <p>23 if I want to --</p> <p>24 Q Okay.</p>	<p style="text-align: right;">Page 212</p> <p>1 lower-thresholds-can-be-appropriate category.</p> <p>2 MS. BOGDAN:</p> <p>3 Q And the same question as it pertains to</p> <p>4 NDEA. Do you consider NDEA to be a mutagen that</p> <p>5 falls outside of the ordinary impurities and</p> <p>6 falls into the lower thresholds category?</p> <p>7 A Yes, I do.</p> <p>8 MS. BOGDAN:</p> <p>9 We can put that exhibit down.</p> <p>10 Q That ICH impurities in drug guideline</p> <p>11 that we just looked at -- and the one we looked</p> <p>12 at was from 2006 -- was that the first guidelines</p> <p>13 that were put out with regard to impurities in</p> <p>14 drug products?</p> <p>15 A Well, it's not referring to impurities</p> <p>16 in drug products. That's Q3B. It's referring to</p> <p>17 impurities in drug substances.</p> <p>18 Q Oh, I'm sorry. I misspoke.</p> <p>19 A Well, it's okay. It's easy to</p> <p>20 interchange the two, so there --</p> <p>21 Q I don't -- I don't want to, though, so</p> <p>22 let me -- let me ask the question again.</p> <p>23 The ICH guideline, impurities in new</p> <p>24 drug substances, the Q3A R2, was that the initial</p>
<p style="text-align: right;">Page 211</p> <p>1 A -- go back to 3 --</p> <p>2 Q Perfect.</p> <p>3 It indicates on notes on attachment 3</p> <p>4 that lower thresholds can be appropriate if the</p> <p>5 impurity is unusually toxic. Do you see that?</p> <p>6 A Yes, I see that.</p> <p>7 Q Okay. And does that pertain to</p> <p>8 mutagenic impurities?</p> <p>9 MR. HARKINS:</p> <p>10 Object to form. Vague.</p> <p>11 A I believe that it's generally</p> <p>12 interpreted that that would apply to unusually --</p> <p>13 to mutagenic impurities.</p> <p>14 MS. BOGDAN:</p> <p>15 Q Do you consider NDMA to be unusually</p> <p>16 toxic --</p> <p>17 MR. HARKINS:</p> <p>18 Object to form.</p> <p>19 Q -- as defined in the guideline?</p> <p>20 MR. HARKINS:</p> <p>21 Object to form. Scope.</p> <p>22 A Unusually toxic. I consider it to be a</p> <p>23 mutagen, and it does -- it falls outside of the</p> <p>24 ordinary impurities and falls into the</p>	<p style="text-align: right;">Page 213</p> <p>1 guidelines for impurities in drug substances,</p> <p>2 that you're aware?</p> <p>3 A No. It's a loaded question in this</p> <p>4 sense. It's -- it's my understanding the Q3A</p> <p>5 before revision 2 --</p> <p>6 And we saw the history that was</p> <p>7 included in the -- in the guidance itself.</p> <p>8 -- it -- it was, what, 1995, I believe</p> <p>9 I saw, when it first came out. That's the first</p> <p>10 Q3 -- that's the first ICH guidance. But there</p> <p>11 were individual guidelines from FDA and other</p> <p>12 regulatory agencies around the world prior to</p> <p>13 that.</p> <p>14 So it -- it's loaded in the sense that</p> <p>15 do you mean ICH or are you saying globally?</p> <p>16 Q Well, let's -- we're -- we're in the</p> <p>17 US, so let's talk about the FDA. Did the FDA</p> <p>18 have guidelines regarding impurities in drug</p> <p>19 substances before the Q3A R2?</p> <p>20 A Yes. Well, before -- and they</p> <p>21 implement their guidance based on Q3A. And</p> <p>22 you're going to R2, which didn't come out till</p> <p>23 much later. But if you go before 1995 and you go</p> <p>24 before ICH was in place, FDA had its own</p>

<p style="text-align: right;">Page 214</p> <p>1 guidances. After Q -- ICH came out, they -- they 2 bring out their guidances based on -- so it's 3 harmonized with ICH Q3A and Q3B. But prior to 4 that, they were -- FDA had guidances on 5 impurities that were their own, for the US only. 6 Q So is it fair to say, at least starting 7 in the 1990s, that the pharmaceutical industry 8 recognized that impurities in drug substances 9 should be recognized? 10 MR. HARKINS: 11 Object to the form. Vague. 12 A It's -- it's known that there were 13 guidance for -- for impurities and that there was 14 attention to impurities and the importance of 15 understanding that in -- from guidelines around 16 the world in various countries, including the 17 FDA. 18 MS. BOGDAN: 19 If we could pull up -- I believe it's 20 document 36 in the repository, which is guidance 21 for industry genotoxic and carcinogenic 22 impurities in drug substances and products. 23 (DEPOSITION EXHIBIT NUMBER 21 24 WAS MARKED FOR IDENTIFICATION.)</p>	<p style="text-align: right;">Page 216</p> <p>1 Q Okay. 2 A Do you want me to look it up? 3 Q Did you actually -- was it one of 4 your -- 5 I see a -- 6 A Yeah. May 2015 revised -- yes. It 7 originally -- 8 It's reference 4 in my expert report, 9 May 2015 I have written down for the first draft, 10 for the first nonrevised version. 11 MS. BOGDAN: 12 We can take this down, this document 13 down. 14 Put up, before we go to the 2015, the 15 document that is number 37 in the repository, the 16 2012 guidance for industry. 17 (DEPOSITION EXHIBIT NUMBER 22 18 WAS MARKED FOR IDENTIFICATION.) 19 MS. BOGDAN: 20 Q Are you familiar with this guidance, 21 Dr. Baertschi? 22 A I am aware of it. I would not call 23 myself familiar with it. I don't have the kind 24 of mastery. I've looked through it, but I -- I</p>
<p style="text-align: right;">Page 215</p> <p>1 MS. BOGDAN: 2 Q Dr. Baertschi, do you see this guidance 3 document? 4 A I do see it. 5 Q Is this -- this is a draft guidance, as 6 you can see from the page, the first page of the 7 document. 8 A Is that a question? 9 Q No. This is a draft guidance. My 10 question is: Was this guidance ever taken out of 11 draft form and issued as a guidance? 12 A I -- I am not 100 percent sure on this, 13 but I don't think it ever was. I think they had 14 a draft guidance, and then I think they withdrew 15 that draft guidance once ICH M7 came out. But 16 I'm not a hundred percent sure on that. 17 Q When did ICH M7 first come out? 18 A I believe it was around 2006. But I 19 prefer, if I'm gonna be nailed down to it, let's 20 take a look at it, because it's right in the 21 guidance itself. 22 Q Okay. Did you reference that guidance 23 in your report? 24 A Yes.</p>	<p style="text-align: right;">Page 217</p> <p>1 don't have real good familiarity with it. 2 Q And does this guidance pertain to the 3 field of analytical chemistry in the 4 pharmaceutical field? 5 MR. HARKINS: 6 Object to form. Vague. 7 A Can you rephrase the question? Because 8 you had a couple of terms in there. You had 9 analytical, and -- and I'm kind of getting lost 10 in the connection. 11 MS. BOGDAN: 12 Q You said you weren't -- or I think you 13 said you didn't have really good familiarity 14 with -- with this particular guidance document. 15 Does this guidance document pertain to the work 16 that you do as a pharmaceutical consultant? 17 A It pertains to it, yes. But it is more 18 intended for a toxicologist because it's really 19 talking about how to set up -- design, set up, 20 and interpret toxicology tests and when -- and 21 what kinds of toxicology tests are needed to 22 qualify impurities and to test for genotoxicity. 23 Q And that isn't anything that you do in 24 the course of your work as a consultant; correct?</p>

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<p>1 A I would agree with that. I -- I have 2 not to date consulted on this guidance or, you 3 know, with any kind of -- other than mostly, 4 like, you know, "let's look at this" and then 5 point them to a toxicologist to further the 6 study. So, no, I don't consult on this. 7 Q Directing your attention to page 19 of 8 this guidance, and, in particular, note 5. 9 A I -- I see it, although it -- oh, now 10 it's on the screen. 11 Q And the first sentence of that note 12 talks about structurally alerting molecular 13 entities are recognized as being causally related 14 to the carcinogenic or mutagenic potential of 15 chemicals. 16 A Is there a question? 17 Q Is one of the structurally alerting 18 molecular entities the nitrosamine functional 19 group that you described earlier in your 20 testimony? 21 MR. HARKINS: 22 Object to form. Scope. 23 A N-nitrosamine, yes. 24 MS. BOGDAN:</p>	<p>1 issued, the first version of it? 2 A Can we go to the history? I want to 3 say it's 20- -- 4 Well, I'd rather just get on the record 5 correctly. Does it have the history here listed? 6 It's before this date. 7 Q I believe under the introduction 8 section it references that the guidance was 9 developed with the expert working group for ICH. 10 A Yeah. So it says it was endorsed by 11 the IC steering committee at step 4, which means 12 it's sort of official at that point in June of 13 2014. 14 Q All right. If we could go to page 5. 15 Actually, what is the purpose of this 16 guidance? 17 A You know, let's take a look. Well, 18 there's a scope. You know, in general terms, 19 it's to provide some -- some assistance, some 20 granularity, some instruction as to how to 21 approach the topic of mutagenic impurities 22 when -- when previously it was essentially 23 undefined. 24 Q And, so, the previous version of this</p>
Page 219	Page 221
<p>1 We can take down this exhibit. 2 If we could please pull up the ICH M7 3 2015 guidance document. It's number 38 in the 4 repository. 5 (DEPOSITION EXHIBIT NUMBER 23 6 WAS MARKED FOR IDENTIFICATION.) 7 A Is -- is this Exhibit 23? Can somebody 8 help me? Or is it 24? 9 MS. BOGDAN: 10 Q Yeah. It's not the one, though, I 11 wanted to mark. 12 Actually, you could pull that -- 13 No. Let's go to -- let's try what's 14 been marked in the repository as number 39. 15 I don't know if that's loaded yet for 16 you, but do you see that guidance for industry? 17 A I see it on my screen. It hasn't 18 loaded yet. 19 I think it has loaded now. Yes, I've 20 got it up now. 21 Q Okay. Are you familiar with this 22 guidance? 23 A I am familiar with this guidance. 24 Q Okay. And when was this guidance first</p>	<p>1 had come out in 2014, and both NDMA and NDEA 2 would fall -- follow under the mutagenic 3 impurities that this document is giving guidance 4 regarding; correct? 5 A I agree with that, yes. 6 Q And if we go to the general principles 7 section, which is on page 5, does it tell us 8 right in the general principles section what the 9 focus of the guidance is? 10 A Yes, it does. 11 Q And what does it tell us the focus of 12 the guidance is? 13 A It says that the focus is on DNA 14 reactive substances that have a potential to 15 directly cause DNA damage when present at low 16 levels, leading to mutations and, therefore, 17 potentially causing cancer. 18 Q And NDMA and NDEA would be DNA reactive 19 substances; correct? 20 A Correct. 21 Q And, then, in that same paragraph, it 22 goes on to say "Therefore, to limit a possible 23 human cancer risk associated with the exposure to 24 potentially mutagenic impurities, the bacterial</p>

<p style="text-align: right;">Page 222</p> <p>1 mutagenicity assay is used to assess the 2 mutagenic potential and the need for controls." 3 Do you agree with that statement? 4 MR. HARKINS: 5 Object to form. Scope. 6 A I agree that that statement is -- I'm 7 reading it, and it -- it's -- it says what it 8 says. 9 MS. BOGDAN: 10 Q The next sentence has "structure-based 11 assessments are useful." 12 What is a structure-based assessment? 13 A It's when you look at the molecular 14 structure of a compound and, based on the 15 moieties or the substructures within that 16 chemic- -- that molecular structure and how 17 they're arranged, can be correlated with, 18 associated with bacterial mutagenicity outcomes 19 from previous testing. 20 So it's a correlation or it's a 21 probability-based assessment based on similar 22 substructures in other compounds. 23 Q And would that be -- type of 24 structure-based assessment be looking for a</p>	<p style="text-align: right;">Page 224</p> <p>1 you to use software to, just -- just looking at 2 the structure, say there is this alerting 3 substructure group in this compound. So you can 4 input a chemical structure and have that software 5 do the work. 6 So they compiled a database to sort 7 of -- and that's where I came up with that number 8 of 31, as I recall. 9 MS. BOGDAN: 10 Q And you relied on that Benigni and 11 Bossa study when writing your report? 12 A I did in that I reference it. It's 13 consistent with other assessments of alerting 14 structures, and I think pretty much every 15 alerting structure list I've seen would contain 16 the -- the cohort of concern and a number of 17 others. 18 The number of 31, it could be some -- 19 it could be 19, it could be 26 -- it sort of 20 depends on how they subdivide certain 21 substructures. But I -- I found that to be a 22 useful sort of comprehensive list of alerting 23 structures. So I did rely on it in that sense. 24 I'm not solely relying on that. It's an</p>
<p style="text-align: right;">Page 223</p> <p>1 structure like N-nitroso functional groups? 2 A Yeah. N-nitroso functional groups are 3 one of the 31-plus alerting structures that would 4 be associated with a risk for mutagenicity as 5 part of that structure-based assessment. 6 Q And is there a list of those 31 7 alerting structures in some type of a guidance? 8 A There are a variety of publications 9 that deal with mutagenic or genotoxic alerting 10 structures. The one that lists them as 31, I 11 believe I reference in my report, and I'm now 12 trying to access in my brain what -- where that 13 was. 14 MR. HARKINS: 15 Do you want to review your report? 16 THE WITNESS: 17 Yeah. 18 MR. HARKINS: 19 Paragraph 30 is where you discuss it. 20 That's what it looks like. 21 A Paragraph 30 I'm looking at. It's an 22 article by Benigni and Bossa, and they took some 23 pains to try to compile them into a -- a series 24 of rules that they built into software to allow</p>	<p style="text-align: right;">Page 225</p> <p>1 illustration of what I'm relying on. 2 Q And of the references that you've read 3 and the ones that you cited in your report, the 4 N-nitroso functional group is one of the alerting 5 structures that's mentioned in those various 6 studies that you're speaking of? 7 A Yes. 8 Q Okay. You mentioned cohort of concern. 9 I see that that concept is, again, from in the M7 10 R1 guidance, and it's in the next paragraph down. 11 And it's towards the bottom of that paragraph 12 where it starts "some structural groups were 13 identified to be of such high potency that 14 intakes even below the TTC would theoretically be 15 associated with a potential for a significant 16 carcinogenic risk." 17 And those structural groups that the 18 guidance is referring to, does that include 19 N-nitroso compounds? 20 MR. HARKINS: 21 Object to form. Compound still. 22 A The next sentence indicates that the 23 cohort of concern includes N-nitroso 24 substructure.</p>

<p style="text-align: right;">Page 226</p> <p>1 MS. BOGDAN:</p> <p>2 Q And N-nitroso substructures would</p> <p>3 include NDMA and NDEA; correct?</p> <p>4 A Correct.</p> <p>5 Q So this guidance to industry is</p> <p>6 alerting the industry of the potential concern</p> <p>7 associated with N-nitroso compounds like NDMA and</p> <p>8 NDEA; correct?</p> <p>9 MR. HARKINS:</p> <p>10 Object to form. Scope. Vague.</p> <p>11 Speculation. Compound.</p> <p>12 A Can you repeat the question? Sorry.</p> <p>13 MS. BOGDAN:</p> <p>14 Q Sure.</p> <p>15 So this guidance to industry is</p> <p>16 alerting the industry of the potential concerns</p> <p>17 associated with N-nitroso compounds like NDMA and</p> <p>18 NDEA; correct?</p> <p>19 MR. HARKINS:</p> <p>20 Same objection.</p> <p>21 A It's certainly alerting -- it's</p> <p>22 certainly calling attention to the cohort of</p> <p>23 concern structures, which include N-nitroso, of</p> <p>24 which NDMA and NDEA are a subset.</p>	<p style="text-align: right;">Page 228</p> <p>1 Off record, 3:38 p.m.</p> <p>2 (OFF THE RECORD.)</p> <p>3 VIDEOGRAPHER:</p> <p>4 On record, 3:52 p.m.</p> <p>5 MS. BOGDAN:</p> <p>6 If you could please pull up exhibit 41</p> <p>7 in the document repository, and if you could give</p> <p>8 me what exhibit we're on to mark it, please.</p> <p>9 TRIAL TECH:</p> <p>10 This will be 24.</p> <p>11 (DEPOSITION EXHIBIT NUMBER 24</p> <p>12 WAS MARKED FOR IDENTIFICATION.)</p> <p>13 MS. BOGDAN:</p> <p>14 Q Dr. Baertschi, let me know when that</p> <p>15 loads.</p> <p>16 A Okay. It's there. It's loading --</p> <p>17 it's there.</p> <p>18 Q Do you recognize Chapter 12?</p> <p>19 A I want to be a smart aleck. I hope so.</p> <p>20 Yes, I recognize it.</p> <p>21 Q And are you the first author of that</p> <p>22 chapter?</p> <p>23 A Yes, I am.</p> <p>24 Q Okay. And what does that chapter</p>
<p style="text-align: right;">Page 227</p> <p>1 MS. BOGDAN:</p> <p>2 Q And this guidance, as we've already</p> <p>3 gone through, first came out in 2014 with ICH;</p> <p>4 correct?</p> <p>5 A I believe that's what we said earlier,</p> <p>6 it was 2014, if my short-term memory serves</p> <p>7 correct.</p> <p>8 MS. BOGDAN:</p> <p>9 Do we want to take a little break? I</p> <p>10 didn't know.</p> <p>11 MR. HARKINS:</p> <p>12 Sure. Do you want five minutes,</p> <p>13 Doctor?</p> <p>14 THE WITNESS:</p> <p>15 Yeah. Let's take five minutes.</p> <p>16 MS. BOGDAN:</p> <p>17 Q I just noticed that you were -- so I</p> <p>18 wanted to offer.</p> <p>19 A Well, muscles are getting a little</p> <p>20 tight here.</p> <p>21 Q Yeah. So if you want to go off for</p> <p>22 five minutes and take a break, we can come back,</p> <p>23 since we're between documents.</p> <p>24 VIDEOGRAPHER:</p>	<p style="text-align: right;">Page 229</p> <p>1 appear in?</p> <p>2 A It's a book on -- by -- on</p> <p>3 specifications of impurities, I think. It has --</p> <p>4 it's a book having to do with --</p> <p>5 I don't remember the exact title of the</p> <p>6 book, but it has to do with specifications.</p> <p>7 Q And your coauthor is a B. Olsen?</p> <p>8 A Yes.</p> <p>9 Q Okay. How do you know --</p> <p>10 What is Dr. -- is it a Dr. Olsen?</p> <p>11 A Yes, it is Dr. Olsen.</p> <p>12 Q Okay. What is Dr. Olsen's first name?</p> <p>13 A Bernard.</p> <p>14 Q Bernard?</p> <p>15 And have you worked with Dr. Olsen</p> <p>16 before?</p> <p>17 A Yes. We were colleagues at Eli</p> <p>18 Lilly & Company.</p> <p>19 Q Does he work for your consulting</p> <p>20 company?</p> <p>21 A He has done some contracts -- some</p> <p>22 subcontracting work, but he's not a part of my...</p> <p>23 So there have been a few projects where</p> <p>24 I didn't have capacity or he was better suited</p>

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1 and I subcontracted that out to him.
2 Q Did you receive any compensation for
3 writing this chapter?
4 A No, unfortunately.
5 Q Who funded the writing of the book?
6 A Who funded? Is that what you asked?
7 Q I did, yes.
8 A The publisher, as far as I know.
9 Q And who was the publisher?
10 A I don't remember. Elsevier, Springer.
11 I can't --
12 MR. HARKINS:
13 Don't guess if you don't know.
14 A I don't remember.
15 MS. BOGDAN:
16 Q I think it's on the bottom. I think
17 you have it right. Else- -- Elsevier?
18 A Elsevier, yes.
19 Q Had you written anything for them in
20 the past?
21 A I'm not completely sure. It's a
22 publishing company. I know I review articles for
23 a --
24 A number of journals are published by

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1 Elsevier, and I'm a referee, scientific referee
2 for a number of journals that are Elsevier
3 published. So -- but I don't know if I've
4 written anything in an Elsevier -- like another
5 book or another book chapter. It's possible.
6 Q Do you receive compensation when this
7 book is sold?
8 A No. I did get a free electronic copy
9 of the book chapter. Oh, I actually received a
10 hard copy of the book as well.
11 Q Oh, good.
12 A Yeah.
13 Q All right. Other than receiving a hard
14 copy of the book, did you receive any
15 compensation for authoring this chapter?
16 A No.
17 Q If you could go to the introduction
18 section.
19 A Yes.
20 Q And in that introduction section, in
21 the first column, it gives a historical context.
22 A Yes. I see that.
23 Q It goes all the way down to saying when
24 the M7 R1 guideline was finalized in 2014,

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1 followed by a revision in September of '17. I
2 don't know if the tech could please put the whole
3 column up.
4 Did you write that section?
5 A Bernie and I did. Bernard, he goes by
6 Bernie.
7 Q Okay.
8 A Bernie Olsen and I co-wrote that
9 chapter. Yes.
10 Q Okay. And, so, I'm assuming you agree
11 with the statements that are contained in this
12 historical context section that has been
13 highlighted for you, the first column?
14 A Yes. Unless I captured some -- unless
15 I captured some error accidentally, we tried to
16 be as accurate as possible and to document the
17 history.
18 Q Okay. And you mentioned in the middle
19 of this --
20 Let's just go through it briefly. You
21 mention for historical context the ICH impurity
22 guidelines, the Q3A, which we have already
23 discussed today -- right? -- previously in your
24 testimony?

Page 233

1 A Yes. Correct. I remember that.
2 Q And the Q3A that you're citing there in
3 this textbook chapter that you wrote is referring
4 to, according to your references, the 2006
5 guidance. And then --
6 A No --
7 Oh, sorry. There wasn't a question.
8 Q Go ahead. 2006 guidance.
9 A Okay.
10 Q But --
11 A Oh, sorry. I did it again.
12 Q But there was -- there was an earlier
13 version of the ICH guidance as well; correct?
14 A Correct.
15 Q That goes back into the '90s that we've
16 previously discussed.
17 A Yes.
18 Q And, then, when you're talking about
19 the ICH impurity guidelines, you actually take a
20 quote right out of those guidelines that read
21 "However, analytical procedures should be
22 developed for those potential impurities that are
23 expected to be unusually potent, producing toxic
24 or pharmacological effects at a level not more

<p style="text-align: right;">Page 234</p> <p>1 than the identification threshold."</p> <p>2 Why was that language actually quoted</p> <p>3 out of the ICH guideline in the book chapter that</p> <p>4 you wrote?</p> <p>5 A Because we were trying to put ICH M7 in</p> <p>6 historical perspective.</p> <p>7 Q And that particular quote from ICH</p> <p>8 impurity guidelines relates directly to M7?</p> <p>9 MR. HARKINS:</p> <p>10 Object to form.</p> <p>11 MS. BOGDAN:</p> <p>12 Q You were trying to show the connection</p> <p>13 from one to the other?</p> <p>14 A In that -- in this book chapter, we are</p> <p>15 trying to show the connection and at least</p> <p>16 suggest the connection that was our understanding</p> <p>17 and somewhat widespread in the industry that --</p> <p>18 that that ICH M7 was anticipated by that phrase</p> <p>19 in Q3A and Q3B.</p> <p>20 Q Okay. And that Q3A was addressing</p> <p>21 mutagenic impurities, and ICH M7 followed that</p> <p>22 original guidance; correct?</p> <p>23 A I don't think I -- I don't think you</p> <p>24 said that correctly. Could you repeat the</p>	<p style="text-align: right;">Page 236</p> <p>1 a thorough toxicological evaluation of potential</p> <p>2 and actual impurities to determine if they are</p> <p>3 indeed a concern for mutagenicity."</p> <p>4 What were you trying to convey with</p> <p>5 that sentence?</p> <p>6 A I -- I'm disappointed that the wording</p> <p>7 itself doesn't make that clear, but I'm trying</p> <p>8 to, I think, suggest that it's a good idea for</p> <p>9 scientists to do a thorough evaluation of both</p> <p>10 potential and actual impurities to see if they</p> <p>11 are a risk for mutagenicity.</p> <p>12 Q Now, on this page 324, which I see on</p> <p>13 the right side of my screen, there is a table</p> <p>14 12.1.</p> <p>15 A I see that.</p> <p>16 Q And it has different classes, impurity</p> <p>17 classifications.</p> <p>18 A Yes.</p> <p>19 Q Are those impurity classifications the</p> <p>20 same that are in ICH M7?</p> <p>21 A I believe so.</p> <p>22 Q Okay. And where do NDMA and NDEA fall</p> <p>23 as far as those classifications?</p> <p>24 MR. HARKINS:</p>
<p style="text-align: right;">Page 235</p> <p>1 question? I think there's an error in what you</p> <p>2 said.</p> <p>3 Q Okay. Well, I'm asking with regard to</p> <p>4 your quoting of the ICH impurity guidelines, were</p> <p>5 you trying to show a relationship between those</p> <p>6 guidelines mentioning potential impurities that</p> <p>7 are expected to be unusually potent and relating</p> <p>8 them to the ICH M7 guidelines that came out</p> <p>9 afterwards?</p> <p>10 A I think that's a fair representation of</p> <p>11 what we were trying to do. We were trying to</p> <p>12 call attention to the fact that it -- that there</p> <p>13 was potentially a connection and that this phrase</p> <p>14 sort of served as a placeholder because it was</p> <p>15 too big of a topic for them to tackle at the time</p> <p>16 ICH Q3A and Q3B, both of those guidances, were</p> <p>17 developed.</p> <p>18 Q Now, let's, if we can, move to the next</p> <p>19 page of your book chapter. And I want to direct</p> <p>20 your attention to section 12.1.3 --</p> <p>21 A Yes.</p> <p>22 Q -- and the last sentence on that page</p> <p>23 in that section which reads "drug development</p> <p>24 scientists are well advised, however, to conduct</p>	<p style="text-align: right;">Page 237</p> <p>1 Object to form. Asked and answered</p> <p>2 with the guidance already.</p> <p>3 But you can answer again.</p> <p>4 A I -- I think there's some controversy</p> <p>5 with whether or not they --</p> <p>6 There's -- this has a class 1 and 2,</p> <p>7 and I think there may be some revisions, and I'm</p> <p>8 not completely sure because I'm not a</p> <p>9 toxicologist. But some question as to whether or</p> <p>10 not they're 1 or 2, if there's a 1A and 1B. I've</p> <p>11 seen a text associated with that from</p> <p>12 toxicologists talking about that. But I -- I</p> <p>13 don't recall myself, don't know how it's been</p> <p>14 formally classified. I have seen it written. I</p> <p>15 just don't recall it for sure.</p> <p>16 MS. BOGDAN:</p> <p>17 Q So as you sit here today, you don't</p> <p>18 know if NDMA or NDEA is a Class 1 known mutagenic</p> <p>19 carcinogen?</p> <p>20 MR. HARKINS:</p> <p>21 Object to form. Scope. Asked and</p> <p>22 answered.</p> <p>23 A Um, from a point of view of a chemist</p> <p>24 dealing with control strategies and any process</p>

<p style="text-align: right;">Page 238</p> <p>1 associated with that, Class 1, 2, or 3, you're 2 gonna deal with it essentially the same, so that 3 the process, the -- that you would undergo, the 4 risk assessment process is -- is the same. 5 Well, if it's a known mutagenic 6 carcinogen, you don't have to do it. You don't 7 have to establish -- it's not exactly the same. 8 But there's -- the implications for 1, 2, or 3 9 are the same. 10 Q And under that table in section 12.2.1, 11 where you have API and DP, the chapter reads 12 "After actual and potential impurities have been 13 identified, a mutagenic risk assessment should be 14 conducted." 15 What did you mean by writing that 16 statement? 17 A Once you have structural knowledge of 18 the chemical structure of an impurity, you should 19 conduct, as outlined in ICH M7, a mutagenic risk 20 assessment. 21 And I would add that if you don't know 22 the structure, you -- you can't really do a 23 mutagenic risk assessment. 24 Q To know the structure, you'd have to</p>	<p style="text-align: right;">Page 240</p> <p>1 MR. HARKINS: 2 Object to form. 3 MS. BOGDAN: 4 Q To your knowledge? 5 A I believe that they're current. I 6 believe that that's the current limits or 7 recommended limits. 8 MS. BOGDAN: 9 You can take that down, please. 10 THE COURT REPORTER: 11 Did you want to make that Exhibit 25? 12 MS. BOGDAN: 13 Yes, please. Any exhibit that I pull 14 up, you're not telling me what they're being 15 marked, but I was assuming they're being marked 16 in consecutive order. 17 MR. HARKINS: 18 I believe they are. 19 TRIAL TECH: 20 Yeah. 21 MS. BOGDAN: 22 If you could please pull up document 42 23 in the document repository, which is the Teva 24 webinar recap.</p>
<p style="text-align: right;">Page 239</p> <p>1 identify it; correct? 2 A Yes. 3 MS. BOGDAN: 4 All right. If we could please take 5 down that exhibit and pull up the control 6 nitrosamine impurities in human drugs, which is 7 number 40 in the document repository. 8 (DEPOSITION EXHIBIT NUMBER 25 9 WAS MARKED FOR IDENTIFICATION.) 10 MS. BOGDAN: 11 Q Doctor, you're aware of this guidance 12 that was issued by the FDA? 13 A Yes, I am. 14 Q Okay. And if I can direct your 15 attention to page 10. Do you see the acceptable 16 intake limit section on page 10? 17 A I do. 18 Q Okay. And table 1 that sets forth the 19 AI limits for NDMA, NDEA, and some other chemical 20 compounds? 21 A I see that. 22 Q Okay. Are those the current acceptable 23 intake limits for those compounds in 24 pharmaceuticals?</p>	<p style="text-align: right;">Page 241</p> <p>1 (DEPOSITION EXHIBIT NUMBER 26 2 WAS MARKED FOR IDENTIFICATION.) 3 MS. BOGDAN: 4 Q Doctor, tell me if you -- if it's 5 loaded for you. 6 A It's loaded. 7 Q Can you see that? 8 Okay. So are you familiar with this 9 webinar, "Nitrosamines: A moving target" that 10 was -- 11 MR. HARKINS: 12 Let her complete her -- 13 MS. BOGDAN: 14 Q -- that was sponsored by Teva? 15 A I -- I think I saw it advertised. I 16 did not log into it. I did not see it. I have 17 not looked at the webinar. 18 Q Well, Teva -- Teva is providing this 19 recap, and it says in the middle of this page, 20 "if you missed the live event, here are your 21 highlights." 22 In this recap document, if we go to the 23 next page, it talks about risk mapping for 24 nitrosamines in the center.</p>

<p style="text-align: right;">Page 242</p> <p>1 Are you familiar with the term "risk 2 mapping"?</p> <p>3 A No. I -- that's a new term for me.</p> <p>4 Q Okay. Well, they describe three steps 5 for nitrosamines risk mapping, and the first step 6 they describe is the theoretical risk assessment.</p> <p>7 Are you familiar with the term 8 "theoretical risk assessment"?</p> <p>9 A Yes.</p> <p>10 Q What is a theoretical risk assessment?</p> <p>11 MR. HARKINS:</p> <p>12 Object to form. Objection to 13 foundation. Object to scope and any questions 14 about this document that he hasn't seen and this 15 concept under a heading that he's already stated 16 he's not familiar with.</p> <p>17 You can answer.</p> <p>18 A Theoretical risk assessment, just 19 piecing together the meaning of all three of 20 those words with the commonly --</p> <p>21 I have some familiarity with risk 22 assessment. Theoretical means it's something 23 that you would do in silico or in cerebro. By 24 that I mean in a computer, where you might use</p>	<p style="text-align: right;">Page 244</p> <p>1 nitrosamines have been found." So --</p> <p>2 And the sentence before that says if a 3 risk is found, then you move to confirmatory 4 testing. Can confirmatory testing be testing to 5 see if a nitrosamine has been formed?</p> <p>6 MR. HARKINS:</p> <p>7 Object to form. Scope. Foundation. 8 Compound. Vague. Calls for speculation.</p> <p>9 A The way you worded it, say could it 10 involve? I guess it could. I really don't know 11 what -- because I don't -- I've not seen that 12 term used before in this context.</p> <p>13 Q Okay. The statement reads "if indeed 14 nitrosamines have been found at higher amounts 15 than the limit, you will need to optimize or 16 change the process before submitting this change 17 to the relevant regulatory agencies."</p> <p>18 Do you agree with that statement?</p> <p>19 MR. HARKINS:</p> <p>20 Object to form. Scope. Foundation. 21 Vague.</p> <p>22 A This is pretty far away from what I've 23 opined on in my expert report, and I don't -- 24 I --</p>
<p style="text-align: right;">Page 243</p> <p>1 theory to theoretically assess, or you use 2 your -- in cerebro, use your brain, your chemical 3 knowledge, your -- your human knowledge to assess 4 theoretically what can you imagine might or will 5 happen or could happen.</p> <p>6 MS. BOGDAN:</p> <p>7 Q And then --</p> <p>8 A Go ahead.</p> <p>9 Q Okay. And then the next item they 10 mention is if risk is found, then you move to 11 confirmatory testing.</p> <p>12 What is confirmatory testing, to your 13 knowledge?</p> <p>14 MR. HARKINS:</p> <p>15 Same objection to scope, foundation. 16 You can answer.</p> <p>17 A I don't know what they mean by 18 confirmatory testing here. There's a potential 19 for a pretty broad range of -- of -- of meaning, 20 because it doesn't fit into the normal 21 terminology I've seen associated with mutagenic 22 risk assessment.</p> <p>23 MS. BOGDAN:</p> <p>24 Q The next sentence, they say "if indeed</p>	<p style="text-align: right;">Page 245</p> <p>1 It's -- it involves some assumptions I 2 would have to make, and I'm getting afield from 3 what I want to comment on. So it's outside the 4 scope of my -- what's it called? -- expert report 5 and what I investigated, what I looked into, what 6 I prepared for.</p> <p>7 MS. BOGDAN:</p> <p>8 Q So is it your testimony that you are 9 not offering any opinions with regard to risk 10 mapping?</p> <p>11 MR. HARKINS:</p> <p>12 Object to form. Scope. Calls for a 13 legal opinion. And objection to the extent it's 14 using the risk mapping term, which he's already 15 stated he's not familiar with.</p> <p>16 A I -- I don't know -- without really 17 understanding the risk mapping process --</p> <p>18 It seems like jargon that's been 19 invented by Teva or somebody that I'm not 20 familiar with, and in that it's a term that I'm 21 not -- generally understand, I would worry about 22 what all it entails, what it means before I would 23 make any kind -- before I would do any kind of 24 review and investigation to try to offer comment</p>

<p style="text-align: right;">Page 246</p> <p>1 on. But I'm certainly not offering comment on 2 that in my expert report or now. 3 MS. BOGDAN: 4 Q The next session on -- section -- 5 excuse me -- on this recap is entitled "risk 6 assessment." And the first statement is 7 "theoretical risk assessment should address all 8 root causes as defined by relevant guidelines and 9 can be grouped into three potential sources for 10 risk with nitrosamines." 11 Do you agree with that statement? 12 MR. HARKINS: 13 Object to form. Object to foundation. 14 Object to the mischaracter- -- or, sorry -- the 15 misstatement of risk assessment as opposed to 16 assessment, as it says in the document. 17 You can answer. 18 A I understand that this is their -- 19 their way of expressing a process that you can 20 use to do risk assessment. I'm not sure I 21 understand everything they're saying. But -- 22 So I -- you know, there's -- there's 23 just some words there that are troubling when you 24 say "should address all root causes as defined by</p>	<p style="text-align: right;">Page 248</p> <p>1 secondary amine doesn't have to be present as it 2 is. It could also be sourced from a 3 primary/tertiary/quaternary amine that is used in 4 the process." 5 Do you agree, as an organic chemist, 6 with that statement? 7 MR. HARKINS: 8 Object to form. Scope. Foundation. 9 Calls for speculation. 10 A There are -- secondary amines are not 11 the only type of amines that can react to form 12 nitrosamines, so limiting your assessment to only 13 secondary amines isn't comprehensive. 14 MS. BOGDAN: 15 Q The next sentence reads "secondary 16 amines can also process intermediates of the API 17 itself." 18 Do you agree with that sentence? 19 MR. HARKINS: 20 Object to form. Scope. Foundation. 21 A I don't think there's anything 22 controversial about that. 23 MS. BOGDAN: 24 Q The next sentence, "Similarly, nitrite</p>
<p style="text-align: right;">Page 247</p> <p>1 relevant guidelines." And I don't know 2 guidelines that define all root causes, and I 3 don't know about the -- if -- the limitation of 4 the three potential sources that they list. So 5 I -- it's getting afield from -- from what I'm 6 here to represent, my expert report. 7 MS. BOGDAN: 8 Q The next paragraph states "nitrosamine 9 formation is attributed to a reaction between the 10 secondary amine and nitrite ion." 11 Do you agree with that statement? 12 MR. HARKINS: 13 Object to form. Foundation. Scope. 14 A I agree that nitrosamines can be formed 15 from reactions of secondary amines and nitrite 16 ions in the right chemical environment because 17 it's not nitrite itself that has the nitrosation. 18 It's a different form of the molecule. And 19 there's more than one nitrosating agent beside -- 20 in addition to nitrite, there are other 21 nitrosating reagents. 22 MS. BOGDAN: 23 Q If we go down to the next paragraph, it 24 reads "It is important to recognize that a</p>	<p style="text-align: right;">Page 249</p> <p>1 can be used itself in the process or it could 2 come from other sources, such as hydroxylamine or 3 nitric acid." 4 Do you agree with that statement? 5 MR. HARKINS: 6 Same objection. 7 A I -- I don't disagree with it. 8 MS. BOGDAN: 9 Q Do you agree that process water should 10 also be assessed for the presence of nitrite 11 ions, as they can react with amines used in the 12 process? 13 A I've seen publications on process 14 water. I know the initial -- the -- the general 15 conservative approach is to say process water 16 should be evaluated. I believe that there's 17 literature out there now that would suggest that 18 there are no instances of that ever happening and 19 that any levels in process water that would 20 contain -- any levels of nitrite that could be 21 contained in process water are so low as to not 22 be significant and that process water can 23 generally be assumed to not have nitrite 24 contamination.</p>

<p>Page 250</p> <p>1 But the fact that they're suggesting 2 that it should be assessed, I don't disagree 3 with. I just don't think it's ever been 4 designated or found as a source of nitrosamine 5 formation in pharmaceuticals. 6 MS. BOGDAN: 7 Go to the next page of this exhibit. 8 It should -- 9 I don't see it. Is there a page in 10 between? Be a second page? That's the third. 11 MR. HARKINS: 12 Looks like it doesn't continue cleanly 13 from one sentence to the other, at least on the 14 copy I'm seeing in the Dropbox. 15 MS. BOGDAN: 16 The top of the second page starts with 17 "remember a secondary amine." That's what I see 18 on my screen. 19 Q Do you agree with the statement 20 "another aspect of potential risk could be 21 contaminated starting materials and solvents, 22 such as recycled solvents or materials that we 23 source from a third party"? 24 MR. HARKINS:</p>	<p>Page 252</p> <p>1 was so long. Can you break it up into two or -- 2 MS. BOGDAN: 3 Q Did you -- did you review any 4 questionnaires that were sent by Teva to Mylan or 5 ZHP that asked them about the potential risks 6 associated with their starting materials or 7 solvents? 8 MR. HARKINS: 9 Object to form. Scope. 10 A I do -- I do not recall reviewing any 11 questionnaires like that. 12 MS. BOGDAN: 13 Q Do you know if any such questionnaires 14 exist -- 15 MR. HARKINS: 16 Object to form. 17 MS. BOGDAN: 18 Q -- as it pertains to valsartan? 19 MR. HARKINS: 20 Object to form. Scope. Foundation. 21 Calls for speculation. 22 You can answer if you know. 23 A I do not know. 24 MS. BOGDAN:</p>
<p>Page 251</p> <p>1 Object to form. Scope. Foundation. 2 A I believe it's been published rather 3 widely that recycled solvents played a role in at 4 least one case of ND -- of N-nitroso 5 contamination and -- and the concept that you 6 could have starting materials that contain -- and 7 solvents that con- -- that bring in with them 8 potential risk is noncontroversial to me. 9 MS. BOGDAN: 10 Q And Teva goes on to say "to address 11 this risk at Teva API, we send dedicated 12 questionnaires to all our vendors and, based on 13 their answers, we conclude whether or not there 14 is a potential risk." 15 In this particular case, did you review 16 any questionnaires that were completed by either 17 Mylan or ZHP that were sent to them by Teva 18 asking about the potential risks associated with 19 starting materials or solvents used in their API 20 synthesis process? 21 MR. HARKINS: 22 Object to form. Scope. Foundation. 23 Compound. 24 A I'm confused by the question because it</p>	<p>Page 253</p> <p>1 We can take this exhibit down. 2 Could we please pull up Teva 59150. 3 And if you don't have it -- 4 I don't see it on this list I have. 5 Can we just go off the record so I can have it 6 sent? 7 MR. HARKINS: 8 Sure. We can take a five-minute break 9 for that. 10 VIDEOGRAPHER: 11 Off record. 4:25 p.m. 12 (OFF THE RECORD.) 13 VIDEOGRAPHER: 14 On the record, 4:29 p.m. 15 MS. BOGDAN: 16 If you could pull up document 59150. 17 (DEPOSITION EXHIBIT NUMBER 27 18 WAS MARKED FOR IDENTIFICATION.) 19 MS. BOGDAN: 20 Q And, Dr. Baertschi, do you see this 21 Teva certificate of analysis for valsartan? 22 A I do. 23 Q On the certificate of analysis, does it 24 outline the different specifications --</p>

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1 A It outlines the --
2 Q -- and tests?
3 Sorry. There's a delay.
4 A Yes. It does outline specification and
5 the associated test for several attributes.
6 Q Okay. And the first tests are called
7 characters?
8 A I see that.

[REDACTED]

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[REDACTED]

Page 256

[REDACTED]

Page 257

[REDACTED]

Page 258

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

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1 [REDACTED]
2 Q And why is gas chromatography good for
3 residual solvent detection?
4 MR. HARKINS:
5 Object to form. Misstates testimony.
6 A Gas chromatography is -- is effective
7 for measuring residual solvents, as a lot of work
8 has been done over the years to develop
9 methodologies to resolve a wide variety of
10 solvents, and solvents are amenable to the
11 separation technique; that is, the
12 volatilization, maintaining themselves in the gas
13 phase while they transverse the column as you
14 heat the column to separate on the basis of
15 certain characteristics and elute off the column
16 of the flame ionization detector or some other
17 detector.
18 MS. BOGDAN:
19 Q So gas chromatography is a good method
20 for detecting volatiles; correct?
21 MR. HARKINS:
22 Object to form. Vague.
23 A Gas chromatography is often used as an
24 effective method to test for volatile compounds.

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1 Volatile compounds can also be amenable to other
2 techniques, such as HPLC. So it sort of depends
3 on what you need to separate, what you need to --
4 You know, it -- it's effective for this
5 particular application of residual solvents.
6 It's been used in many cases, in many industries
7 for that.
8 MS. BOGDAN:
9 Q And gas chromatography can be used to
10 detect NDMA, can't it?
11 A Yes.
12 Q And gas chromatography can be used to
13 detect NDEA, can't it?
14 MR. HARKINS:
15 Objection --
16 A I'm sorry. I --
17 I'm sorry.
18 MR. HARKINS:
19 Objection. Scope. Objection. Vague.
20 Calls for speculation.
21 A I need to clarify. Gas chromatography
22 doesn't detect anything itself. It only
23 separates things. The detector comes after the
24 separation of the gas chromatograph. So the

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1 detector is completely different. It's not part
2 of gas chromatography. It's hyphenated GC/FID,
3 GC/MS, GC/specialized detector, nitrogen,
4 phosphorous. There's many GC detectors. I'm
5 just clarifying.
6 So if you want to restate your
7 question, if I didn't answer it, I'm happy to
8 address it.
9 MS. BOGDAN:
10 Q Is gas chromatography an effective
11 technique for separating an NDMA impurity from
12 valsartan?
13 MR. HARKINS:
14 Object to form. Vague.
15 A You can get some specificity because
16 valsartan, I don't believe, volatilizes very
17 easily. So it -- you're -- it -- as a matrix
18 background, it's kind of removed, and you'll
19 typically only see the residual solvents that are
20 present instead of the massive amount of
21 valsartan. So, in that sense, it's -- it's --
22 it's one useful way of separating NDMA or NDEA
23 from valsartan.
24 MS. BOGDAN:

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1 WAS MARKED FOR IDENTIFICATION.)

2 MS. BOGDAN:

3 Q While they're pulling up that document,

4 Dr. Baertschi, did you review the synthetic route

5 of synthesis process that was being used by the

6 API manufacturers to produce the valsartan API

7 that was being sold in the Teva finished-dose

8 product?

9 A Yes. The term "review it" is

10 potentially loaded because typical process

11 chemists, when they review a synthetic route,

12 they'll look at the actual process, procedure.

13 In this case, the procedure -- the

14 overall process is represented by these

15 illustrations on this figure. And in terms of

16 looking at the figure and thinking about the

17 chemistry that they use to assemble the atoms

18 together and the molecule, yes, I did review it

19 in that sense.

20 But I didn't review it for, you know,

21 for the purposes of trying to understand all the

22 chemistry associated with the synthetic route.

23 Q This synthetic route that is

24 illustrated on the exhibit that's marked --

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1 MS. BOGDAN:

2 What number is this, please?

3 TRIAL TECH:

4 29.

5 MS. BOGDAN:

6 Q -- that's marked as Exhibit 29 has a

7 crude synthesis step. Do you see that?

8 A I do see that.

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 Q And is sodium nitrite one of the

14 chemicals that is known to potentially produce

15 nitrosamines?

16 MR. HARKINS:

17 Object to form. Vague. Speculation.

18 A Sodium nitrite is known that in the

19 acidic form, the HONO that nitrous acid form, it

20 can N-nitrosolate amines.

21 MS. BOGDAN:

22 Q And when you say can N-nitrosolate

23 amines, does that mean form nitrosamines?

24 A Yes.

Page 268

1 [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 Q And the triethylamine combined with

13 sodium nitrite, is that something, as an organic

14 chemist, alerts you to the possible formation of

15 NDEA?

16 MR. HARKINS:

17 Object to form. Vague.

18 A Well, it's kind of tricky in that

19 you're normally, when you're doing this kind of

20 analysis historically, you're looking at

21 triethylamine and you're thinking about the main

22 component and you're not thinking about trace

23 level impurities in that reagent.

24 Sodium nitrite is a common workup

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1 procedure for getting rid of excess azide

2 historically. It's been used frequently for

3 that. And now they've discovered that this --

4 this reaction happens and -- and that it's --

5 that surprised everybody, so the -- the -- the --

6 It's not obvious at first glance that

7 you have to think about that a low-level

8 potential impurity reacting with sodium nitrite.

9 In hindsight, now, it's more obvious because

10 there's been all this noise -- all this

11 information in -- in the regulatory system about

12 the formation of nitrosamines that hadn't been

13 observed before.

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 Q And sodium nitrite, we know from

19 earlier on in the deposition, is known to

20 potentially cause nitrosamine formation; correct?

21 A When -- when it's in the presence of an

22 amine, typically secondary amine, and -- and

23 there are acidic conditions.

24 Q We also know from earlier in the

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1 deposition that N-nitrosamines can form from
2 secondary amines, tertiary amines, or quad- --
3 quad amines; correct?
4 MR. HARKINS:
5 Object to form. Asked and answered.
6 Compound.
7 A Yes.
8 MS. BOGDAN:
9 If we could please pull up 74773.
10 (DEPOSITION EXHIBIT NUMBER 30
11 WAS MARKED FOR IDENTIFICATION.)
12 MS. BOGDAN:
13 Q Dr. Baertschi, this is the ZHP
14 synthetic route for the zinc chloride process.
15 Have you looked at this?
16 A I have seen this before, and I.
17 Q ...this before?
18 A I'm sorry. I interrupted you. Could
19 you repeat the question?
20 Q Have you seen this before?
21 A Yes, I've seen that synthetic route
22 before. I don't know if I've seen this exact
23 page or this exact representation of it, but I
24 have seen the -- the synthetic route represented

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1 before.
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 A Dimethylformamide.
14 Q And what is that?
15 A A solvent used in organic chemistry a
16 lot to -- tends to be an inert solvent so that
17 you can conduct reactions between molecules where
18 the solvent doesn't generally get involved.
19 Q Isn't it known that DMF can decompose
20 to result in dimethylamine?
21 MR. HARKINS:
22 Object to form. Scope.
23 A There is information in the literature
24 and elsewhere that DMF can have an impurity in it

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1 and can decompose to dimethylamine under the
2 right --
3 MS. BOGDAN:
4 Q And that --
5 A Sorry.
6 Q And dimethylamine with sodium nitrite
7 can form NDMA; correct?
8 A Yes. In the presence of acidic
9 conditions, that reaction could occur.
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

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1 [REDACTED]
2 Q And --
3 A And I -- I would -- I would offer this.
4 I'm not a chemical process -- I'm not a process
5 chemist, and I haven't been asked to assess these
6 synthetic routes for, you know, for this kind of
7 chemistry. I think it's kind of been published
8 widely, globally in the literature, and that's
9 where I first learned about this before I was
10 ever retained in this case. So it's not
11 completely new to me.
12 But I'm not a chemical process -- a
13 process chemist, although I can understand the
14 representations because I do have an organic
15 chemistry background. But I'm also not really
16 opining on that in my expert report.
17 Q Do you know how NDMA was first
18 discovered in valsartan?
19 MR. HARKINS:
20 Object to form. Scope.
21 A My -- I do not know. My -- the hearsay
22 or what I've read in some disclosures maybe
23 inside this case but probably outside this case,
24 that I recall Novartis was the first one to

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1 discover it or detect it. But I don't know that
2 to be the case.
3 MS. BOGDAN:
4 Q Did counsel provide you with documents
5 from Novartis showing how NDMA was first
6 discovered in valsartan?
7 MR. HARKINS:
8 Object to form. Scope.
9 You can answer to the extent it doesn't
10 reflect discussions you had with counsel.
11 A I don't remember if I've seen a
12 document or if there was a document that
13 disclosed that. It's -- I don't remember if I
14 have. It's possible, but I don't think so.
15 MS. BOGDAN:
16 If we could pull up ZHP4399.
17 (DEPOSITION EXHIBIT NUMBER 31
18 WAS MARKED FOR IDENTIFICATION.)
19 MS. BOGDAN:
20 And if you can't find that one, why
21 don't we pull up ZHP388639, which is number 48,
22 potentially.
23 Could I have a time check?
24 VIDEOGRAPHER:

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1 Six hours, five minutes.
2 MS. BOGDAN:
3 Q Let me know, doctor, once you see that,
4 if it loads up on your screen.
5 A I think it's Exhibit 31. I think it
6 just loaded up on my screen. I think it's the
7 right one.
8 MR. HARKINS:
9 That's right. It's Exhibit 31. That's
10 what I have.
11 A Yeah. Okay. Looks like I've got it.
12 MS. BOGDAN:
13 Q Do you have it on the screen?
14 Okay. Because we're using this
15 document, we're gonna have to go to a later page
16 in the document. Go to the -- just trying to
17 orient myself here, because the other document
18 wasn't in the box here. Just hold on a second
19 here.
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

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1 [REDACTED]
2 [REDACTED]
3 MR. HARKINS:
4 Object to form. Scope. Foundation.
5 Calls for speculation.
6 Doctor, please take any time that you
7 need to review the rest of this document,
8 including any of the other emails that are
9 attached, before you answer, to the extent you
10 think it's necessary.
11 A Okay. Are these emails sequentially
12 from the most recent to the oldest, like top
13 down?
14 Oh, there's a lot of them.
15 MS. BOGDAN:
16 Q Yes, I believe so.
17 A Yeah. Are you asking a question
18 unrelated to this entire document? You're asking
19 a question what would --
20 Could you restate the question?
21 Q Sure.
22 What should a scientist that is
23 operating a gas chromatography test on valsartan
24 do if there are unknown peaks?

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1 MR. HARKINS:
2 Object to form. Scope. Foundation.
3 Incomplete hypothetical. Calls for speculation.
4 A Yeah, I don't --
5 Just having an unknown peak doesn't
6 call for necessarily anything unless that unknown
7 is above a level where it should be reported and
8 unless there is some kind of criteria associated
9 with it being a level of identification threshold
10 or qualification threshold. So it would -- it
11 would depend on more information as to what you
12 would do, what would be the -- a scientist would
13 be expected to do.
14 But there's not a default that anytime
15 you see an unknown in GC or HPLC that you should
16 automatically do something.
17 MS. BOGDAN:
18 Q Okay. Fair enough. Why don't --
19 If we could go to the -- 1, 2, 3 -- I
20 think it's page 7 of this document. And we're
21 going to go to the email on the bottom.
22 When it says "valsartan ESO," do you
23 know what is meant by ESO?
24 MR. HARKINS:

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1 Object to form. Scope. Foundation.
2 A I'm afraid I do not know what ESO means
3 in this context.
4 MS. BOGDAN:
5 Q If we could go to the next page,
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

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1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 MS. BOGDAN:
7 Okay. Could we please pull up document
8 190079.
9 (DEPOSITION EXHIBIT NUMBER 32
10 WAS MARKED FOR IDENTIFICATION.)
11 MS. BOGDAN:
12 Q Dr. Baertschi, do you know what type of
13 testing Novartis was doing when it discovered
14 NDMA in the valsartan API?
15 MR. HARKINS:
16 Object to form. Scope. Foundation.
17 Facts not in evidence. Asked and answered.
18 A I do not know.
19 MS. BOGDAN:
20 Q Did you ask to review documents to
21 figure out what testing was done that resulted in
22 the discovery of NDMA in valsartan API?
23 MR. HARKINS:
24 Object to form. Scope. Foundation.

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1 You can answer to the extent it doesn't
2 reflect discussions with counsel.
3 A I -- I do not recall asking that
4 question.
5 MS. BOGDAN:
6 Q Would it be important to you when
7 rendering your opinion in this case to know what
8 type of testing was being done that resulted in
9 the discovery of NDMA in valsartan?
10 MR. HARKINS:
11 Object to form. Scope. Vague.
12 Foundation.
13 A Um, you're asking would it be of
14 interest to me to know how it was discovered,
15 what testing was being done by Novartis. It --
16 it doesn't affect -- it -- I don't -- it doesn't
17 affect my opinion in that what I looked at is --
18 is the normal routine of how you -- a
19 finished-dose provider goes about and what
20 information they had this ability to.
21 So could -- could information like that
22 be interesting? I find it -- I would find it
23 interesting as a scientist.
24 MS. BOGDAN:

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1 Q But you didn't ask for that information
2 when formulating your opinions in this case?
3 MR. HARKINS:
4 Same objection. Also asked and
5 answered.
6 A I don't recall asking that question. I
7 really -- I really do not know -- I did not know
8 how Novartis --
9 The role Novartis played in that was
10 opaque to me.
11 MS. BOGDAN:
12 Q If Novartis discovered the NDMA in
13 valsartan when doing residual solvent testing by
14 gas chromatography and found an unknown peak
15 which they then investigated and determined what
16 that unknown peak was, that would not be of
17 interest to you when forming an opinion with
18 regard to the type of testing that would reveal
19 NDMA in valsartan?
20 MR. HARKINS:
21 Object to form. Scope. Vague.
22 Foundation. Calls for speculation. Assumes
23 facts not evidence. Misstates the witness's
24 testimony.

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1 A If Novartis discovered NDMA in
2 somebody's lots by doing residual solvent testing
3 and then some follow-up investigation, I would
4 want to know more details, and it would be of
5 interest to me scientifically. I don't know that
6 it would affect my opinions or the relevance to
7 my report.
8 MS. BOGDAN:
9 Q Is it your opinion that finding NDMA or
10 NDEA in valsartan can't be determined by using
11 gas chromatography and mass spectrometry?
12 MR. HARKINS:
13 Object to form. Scope.
14 A Well, there's a problem with, one, when
15 you're doing residual solvents testing, it's
16 typically done with a flame ionization detector,
17 which doesn't give you any structural molecular
18 information, and the peak sizes are generally
19 related with FID, to the number of carbon atoms
20 in there, so it's hard to know what's significant
21 in terms of an amount.
22 If there was a small peak that Novartis
23 decided to go after for some particular reason, I
24 don't know enough information to know if that was

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1 compelling. It's -- it's -- it's o- -- it's too
2 vague. It's too opaque. I would -- I would need
3 to actually have that laid out for me to -- to
4 understand it.
5 And -- and, further, when you go to
6 GC/MS analysis for NDMA, that's got the same
7 molecular weight as DMF, so you could get
8 confused and just see a peak and say, okay,
9 that's just DMF. So it's -- or you could
10 overestimate because you're -- you're co-eluting,
11 you're -- you're -- you're not -- you're not
12 separating completely out, so you could get
13 convoluted results.
14 So I'm not sure if I've fully answered
15 your question or not. I'm trying to.
16 MS. BOGDAN:
17 Q Right.
18 With regard to Novartis, if this, what
19 I'm questioning you about it, is too vague or too
20 opaque, would it have been less vague if you had
21 been given the documents to show what testing
22 Novartis did that resulted in the discovery of
23 NDMA in valsartan?
24 MR. HARKINS:

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1 Object to form. Scope. Vague.
2 Assumes facts not in evidence.
3 A Um, it -- it's possible. I don't know
4 because there's so many unknowns. It could be
5 that, say -- I don't know. If I looked at it,
6 it's like I don't know how Novartis decided to
7 investigate an unknown peak or why. But if I
8 did, it would -- I would evaluate it
9 scientifically and as best I could.
10 MS. BOGDAN:
11 Q But as part of you arriving at your
12 opinion in this case, you were not provided with
13 the reports from Novartis showing the testing
14 that they did which resulted in the discovery of
15 NDMA; correct?
16 MR. HARKINS:
17 Object to form. Scope. Facts not in
18 evidence. Asked and answered for the fourth time
19 now.
20 A I'm not sure if I was provided any
21 documents. There was literally more than a
22 hundred, maybe hundreds -- I'm not completely
23 sure -- documents that were made available to me,
24 and they gave me free reign through the

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1 documents. But I can't -- I can't claim that
2 they were not provided to me. I just don't know.
3 MS. BOGDAN:
4 Q Well, let's look at the exhibit that
5 has been put up on the screen, which is a report
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

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[REDACTED]

Page 287

[REDACTED]

Page 288

[REDACTED]

8 MR. HARKINS:

9 Object to form. Scope. Foundation.

10 Again, please review anything you need

11 to answer the question.

12 A Could you restate that question? Could

13 you restate the question?

14 MS. BOGDAN:

15 Q Have you seen this -- this particular

16 report ever before?

17 A I don't know.

18 Q You don't know if you've ever seen

19 this --

20 A I've seen some residual solvent results

21 in the reports. I don't know if it was this one.

22 I don't think so. But I've seen a -- a

23 chromatogram somewhere of residual solvents for

24 valsartan.

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1 But there is no table on the --

2 question on the table, is there?

3 MR. HARKINS:

4 No. Just wait.

5 MS. BOGDAN:

6 Q No, other than I asked if you've ever

7 seen this.

8 If you could go to the instrument

9 methods that were being used --

10 Do you know who Solvias is? Have you

11 ever worked with that company before?

12 A It's Solvias.

13 I haven't personally worked with them,

14 but I'm familiar with them as a company and what

15 they -- some of the things they offer.

16 Q And what does Solvias --

17 Or "Sol-val-is," did you say?

18 What do they do?

19 A Solvias.

20 I think they're a contract research

21 organization where they do specific types of

22 laboratory analyses as a contract lab. I think

23 they made some fame -- their -- I think they used

24 to be known for polymorph screening, but they --

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1 they may do a lot more than that.

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 [REDACTED]

20 [REDACTED]

21 [REDACTED]

22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

Page 291

1 [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 Why is a sample compared to a reference

12 solution when doing a chromatogram?

13 MR. HARKINS:

14 Object to form. Scope. Foundation.

15 Calls for speculation.

16 You can answer.

17 A So there -- typically, when you have

18 a -- a peak you want to -- a compound that you

19 know and you want to establish where it elutes or

20 where it -- the retention time for it, you -- and

21 for the various components, you'll have a -- a

22 sample made up with the various impurities that

23 you're trying to establish so that you can -- at

24 levels that you can detect and see. So you

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1 establish where they -- where they are in the

2 chromatogram.

3 MS. BOGDAN:

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 [REDACTED]

20 [REDACTED]

21 [REDACTED]

22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

Page 293

1 [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 [REDACTED]

20 [REDACTED]

21 [REDACTED]

22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

<p style="text-align: right;">Page 298</p> <p>1 MR. HARKINS: 2 Object -- 3 THE WITNESS: 4 Sorry. 5 MR. HARKINS: 6 Object to form. Vague. 7 A Familiar -- am I familiar? I am aware 8 of the USP. I have given talks there. I've 9 given a workshop there. I've been on a couple of 10 USP expert committees. 11 MS. BOGDAN: 12 Q So the USP, on their website, with 13 regard to nitrosamine impurities, writes 14 "companies are responsible for understanding 15 their manufacturing processes, which includes 16 identifying and preventing the presence of 17 unacceptable impurities." 18 Do you agree with that statement made 19 by USP? 20 MR. HARKINS: 21 Object to form. Foundation. Vague. 22 You can answer. 23 A I can't -- 24 Company -- what comp- --</p>	<p style="text-align: right;">Page 300</p> <p>1 statement that companies that manufacture drug 2 products are responsible for understanding their 3 manufacturing processes, which include 4 identifying and preventing the presence of 5 unacceptable impurities? 6 MR. HARKINS: 7 Object to form. Outside the scope of 8 his expert report. Foundation. 9 You can answer. 10 A Yeah. It seems to be getting into some 11 regulatory and quality aspects for which I've not 12 formed an -- I've not investigated or been asked 13 to opine on, and I think there are -- 14 Unfortunately, that statement can be 15 expanded to mean something I wouldn't want it to 16 mean, so I'm uncomfortable with agreeing with it. 17 MS. BOGDAN: 18 Q The next sentence that the USP has is 19 "this involves developing new predictive 20 approaches along with using suitable methods to 21 detect and control these impurities, as well as 22 others that may arise when making changes to the 23 manufacturing process." 24 Do you agree with that statement made</p>
<p style="text-align: right;">Page 299</p> <p>1 To the extent if you were to define 2 companies, there's something implied there that's 3 not specifically stated, and I -- I -- I don't 4 want to speculate on what they're implying. But 5 company A and company B and company Z are not 6 equally responsible. So Google is not 7 responsible for something that company A in some 8 other country did in a different field. So it 9 depends on what kind of company you're talking 10 about the relationship. So in that -- to that 11 extent, I think there's some vagarity there. But 12 certainly it's an important thing to understand 13 manufacturing processes, which includes 14 identifying and preventing presence of -- 15 preventing or minimizing -- 16 I don't like "preventing" because 17 they're not always preventable. 18 -- presence of -- 19 "Unacceptable," that's another vague 20 term. 21 -- impurities. So they're kind of 22 using loaded jargon there. 23 Q Well, if we say companies that 24 manufacture drug products, do you agree with the</p>	<p style="text-align: right;">Page 301</p> <p>1 by the USP? 2 MR. HARKINS: 3 Object to form. Scope. Foundation. 4 Vague. 5 A That sentence seems to be aspirational 6 in its nature and encouraging the industry to 7 innovate to -- to do things to ensure safety and 8 to ensure purity. It's -- it's not a legal 9 statement, and it's more of a -- a statement to 10 have encouraged to, to -- to encourage companies 11 to innovate and to develop and to consider. 12 MS. BOGDAN: 13 Q Well, you relied on the USP 14 monograph -- correct? -- when providing your 15 opinion in this case? 16 A Yes. USP monographs are carefully 17 reviewed and -- peer-reviewed. This is a 18 statement on their website that doesn't to me -- 19 I'm not a lawyer, but it doesn't have 20 sort of -- 21 It's just general jargon that you can 22 interpret in multiple -- multiple ways. For 23 example, it involves developing new predictive 24 approaches. That's kind of all aspirational and</p>

<p style="text-align: right;">Page 302</p> <p>1 vague and difficult to say what that means. 2 So do I agree with new predictive 3 approaches can help manufacturers control 4 impurities? Absolutely. 5 Q Do you agree that manufacturers of 6 drugs should have suitable methods to detect and 7 control NDMA and NDEA in their drug products? 8 MR. HARKINS: 9 Object to form. Outside the scope of 10 his expert report. Foundation. Vague. 11 A What you're suggesting is that all 12 manufacturers of all drugs should have an 13 analytical method to test for NDMA and NDEA, 14 whether or not it's been established it's even 15 vaguely relevant. And if you're gonna do that 16 for NDEA and NDMA, you're gonna need to do it for 17 all the other cohort-of-concern compounds and all 18 the other compounds in -- in the alerting 19 structures, those 31 groups, because you -- you 20 would be like fishing for -- you'd have to have 21 methods for everything. So you can't just have 22 methods for -- 23 I've established this well in my 24 report, that to have the expectation that no</p>	<p style="text-align: right;">Page 304</p> <p>1 the synthetic route. 2 So to say that a specific NDMA after -- 3 post-2018 retrospectively, in hindsight, looking 4 back, it's kind of easy to point at that being 5 something that -- that should be done. But to 6 predictively anticipate that would mean that the 7 rest of the world -- the world wouldn't have -- 8 it would have been expected. 9 And it's clear that the entire world, 10 all the regulatory agencies, every company, 11 this -- this occurrence was a surprise to them. 12 And now it seems like we're trying to frame that 13 as that it -- it was, in the case of Teva, 14 everybody else -- 15 They're the -- they're the ones that 16 should have figured it out and never let it 17 happen. Is it a surprise? How could it be 18 unexpected if it's not a surprise? 19 So, in hindsight, we've learned 20 something as an industry. But if we go back to 21 2018 and before, it was -- it was not sur- -- it 22 was unexpected. It was a surprise. 23 MS. BOGDAN: 24 Q If a company knew that NDMA or NDEA</p>
<p style="text-align: right;">Page 303</p> <p>1 mutagenic impurity can escape detection in any 2 synthetic route is -- is not realistic for any 3 manufacturer that's ever manufactured drugs on 4 the earth or now. 5 So I do not agree that all 6 manufacturers should have a method for NDMA and 7 NDEA for all of their drug products. 8 MS. BOGDAN: 9 Q Sodium nitrite is being used in the 10 chemical synthesis process to create the drug. 11 Should a manufacturer have developed a method to 12 detect whether NDMA or NDEA has been formed in 13 that chemical synthesis process? 14 MR. HARKINS: 15 Object to form. Scope. Incomplete 16 hypothetical. Calls for speculation. Vague. 17 A That -- that is kind of a loaded 18 question that has all the assumptions built into 19 it. It's -- it's easy -- 20 And nit- -- and sodium nitrite doesn't 21 just have the potential for creating NDMA and 22 NDEA. It has the potential for creating a vast 23 assortment of N-nitroso compounds depending on 24 any amine that might be present at any level in</p>	<p style="text-align: right;">Page 305</p> <p>1 could form in valsartan, then, under those 2 circumstances, would you agree that they should 3 have had a method to detect NDMA and NDEA? 4 MR. HARKINS: 5 Object to form. Outside the scope of 6 his expert report in the class certification 7 phase of the case. Vague. Incomplete 8 hypothetical. Calls for speculation. 9 A Yeah. It seems to be getting far 10 afield. I'm, like, being pulled into some kind 11 of a synthetic expert that can do a comprehensive 12 process risk assessment and make a pronouncement 13 when I haven't been asked to look into that, and 14 I don't offer that as a consulting service 15 myself. 16 And I think when you have some 17 suspicion that a nitrosamine might be formed, it 18 should be considered as part of your due 19 diligence risk assessment for the formation of 20 nitrosamines, and that process should lead you to 21 decide whether or not a method is needed. And it 22 may very well be that at times it could be needed 23 or will be needed, but not in -- not in every 24 case. Not as a blanket statement.</p>

<p>Page 306</p> <p>1 MS. BOGDAN: 2 Will you please pull up document 58? 3 Or -- excuse me -- 57, the valsartan USP 4 monograph. 5 (DEPOSITION EXHIBIT NUMBER 34 6 WAS MARKED FOR IDENTIFICATION.) 7 MR. HARKINS: 8 Do you have it in your exhibit box? 9 THE WITNESS: 10 No. Is it 33, 34? 11 MR. HARKINS: 12 I think it will be 34. 13 THE WITNESS: 14 Yes. It just came up, and it's now up. 15 MS. BOGDAN: 16 Q Are you familiar with the USP monograph 17 for valsartan? 18 A Yes. I have looked at this -- I have 19 looked at this and considered it. 20 Q And this is the current USP monograph 21 for valsartan; correct? 22 A It says, on the top, "official status," 23 currently official as of January 28th. So I 24 would presume -- they don't change those very</p> <p>Page 307</p> <p>1 often, so I presume that that's official as of 2 now. 3 Q And with your review of the document, 4 it's the monograph that you're familiar with? It 5 looks familiar to you? 6 A It looks familiar. I don't know 7 what -- 8 What I viewed was the current -- 9 Let's see. When was this updated? 10 Official date as of May 2020. So this has been 11 revised since -- 12 This is -- this is official as of May 13 2020, which implies that there was a different 14 monograph in place as of 2018. 15 Q But this -- even though it is now 16 common knowledge in the industry that NDMA and 17 NDEA were found in valsartan, the monograph still 18 does not address those mutagenic impurities, does 19 it? 20 A I don't see any reference to 21 nitrosamines, NDMA -- any nitrosamine referenced 22 as I skim through it. 23 Q And this was published after the 24 recalls of valsartan, when it was known that NDMA</p>	<p>Page 308</p> <p>1 and NDEA were found in the drugs; correct? 2 A Yes. It was published May 1st, 2020. 3 So that's after. 4 Q And the FDA has said that valsartan 5 cannot be sold if it has more than 96 nanograms 6 of NDMA in it; correct? 7 A I believe that's the implication of 8 their limit. I don't actually know the legal 9 aspect of what they can or can't sell or, if they 10 could sell it, they'd be at risk. I'm not 11 exactly sure of the legal implication. But that 12 appears to me to be what is -- what they want by 13 having that limit. 14 Q And this monograph does not -- by 15 complying with this monograph, it doesn't relieve 16 a manufacturer of having to also comply with the 17 acceptable intake limit set by the FDA for NDMA 18 or NDEA, does it? 19 MR. HARKINS: 20 Object to form. Scope. 21 A This -- this -- this monograph would 22 not supersede or cut out the responsibility of -- 23 you could not ignore the NDMA, NDEA requirements 24 because they're not listed in this updated</p> <p>Page 309</p> <p>1 monograph. 2 MS. BOGDAN: 3 Can I have a time check, please? 4 VIDEOGRAPHER: 5 Six hours, 50 minutes. 6 MS. BOGDAN: 7 Can we just take a short break, five 8 minutes? 9 MR. HARKINS: 10 Sure. How much more do you think you 11 have? 12 MS. BOGDAN: 13 Not much. I just want to review my 14 notes. 15 MR. HARKINS: 16 Sure. 17 VIDEOGRAPHER: 18 Off record, 5:46 p.m. 19 (OFF THE RECORD.) 20 VIDEOGRAPHER: 21 On record, 6 p.m. 22 (DEPOSITION EXHIBIT NUMBER 35 23 WAS MARKED FOR IDENTIFICATION.) 24 MS. BOGDAN:</p>
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1 Q Dr. Baertschi, I want to show you what
2 I believe is being marked as Exhibit 35 for
3 identification.

⁴ A It's not shown up in the Dropbox yet,
⁵ but...

⁶ Q Well, let me ask you this question in
⁷ the meantime, while the document is being loaded.

8 Did you rely, when formulating your
9 opinions in this case, on all the materials
10 listed in your amended materials considered list?

11 A It -- it depends on your definition of
12 "rely," because all of the materials listed, I --
13 I tried to go through them all, and they were
14 certainly accessible to me. There were a number
15 of documents where I'm looking through and I'm
16 saying, eh, there's nothing here that really
17 informs me to my opinion. So I can't say that
18 all of them informed me. So in that sense of
19 relying, that's how I would classify it.

20 Q Meaning some of them you did not rely
21 on.

22 MR. HARKINS:

23 Object to form to the extent it calls
24 for a legal conclusion.

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¹ You can --

2 A I -- I sort of want to stand by the way
3 I framed it, is that not all the documents were
4 informative, and, so, I -- so I didn't --

5 The ones that weren't informative, if
6 you call that relying? I would call it it didn't
7 affect my opinion or my opining.

8 I don't know what you mean by "rely,"
9 so --

10 So I'm not trying to be evasive. I'm
11 trying to protect myself from saying something
12 incorrect. I tried to be as comprehensive as I
13 could with the documents provided me, which were
14 extensive, and the materials that we've cited,
15 which are comprehensive.

¹⁶ MS. BOGDAN:

17 Q Turning your attention to what's been
18 marked as Exhibit 35 for identification, which is

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1 A Oh, yes.
2 Q Did you seek to get answers to your
3 questions?
4 A How do you seek --
5 MR. HARKINS:
6 Object to form. Vague.
7 You can answer.
8 A No. I don't have any way to get
9 answers to my questions.
10 MS. BOGDAN:
11 Q Did you ask for any further documents
12 that would be surrounding this document to answer
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 MR. HARKINS:
17 Object to form. Scope. Foundation.
18 You can answer to the extent it doesn't
19 reflect conversations with counsel.
20 A I -- I have not asked for any documents
21 associated with this.
22 MS. BOGDAN:
23 Q You are aware, as an expert in this
24 case, that Novartis discovered NDMA in valsartan

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1 API; correct?
2 MR. HARKINS:
3 Object to form. Asked and answered.
4 Can I get a time check?
5 VIDEOGRAPHER:
6 I have seven hours and one minute.
7 MR. HARKINS:
8 You can answer the question, Doctor.
9 A Repeat the question, please. I'm
10 sorry.
11 MS. BOGDAN:
12 Q Sure.
13 ...as an expert in this case, that
14 Novartis discovered NDMA in valsartan API;
15 correct?
16 MR. HARKINS:
17 Same objection. Asked and answered.
18 A That is my understanding, that Novartis
19 discovered NDMA in valsartan. But I don't know
20 that to be a fact, but that's my understanding.
21 MS. BOGDAN:
22 Q And it's your opinion --
23 MR. HARKINS:
24 Rosemarie, we don't have a question

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1 pending. We're over the 7-hour time limit. We
2 are way outside the scope, and we're doing things
3 that he's asked and answered multiple times
4 today.
5 We'll be back in about ten minutes,
6 because I will have a redirect.
7 Doctor, you can put your camera on
8 mute.
9 VIDEOGRAPHER:
10 Off record, 6:12 p.m.
11 (OFF THE RECORD.)
12 VIDEOGRAPHER:
13 On record, 6:42 p.m.
14 EXAMINATION
15 BY MR. HARKINS:
16 Q All right. Dr. Baertschi, I am going
17 to ask you some questions now. If you'd go ahead
18 and --
19 You have your expert report with you;
20 right?
21 A Yeah.
22 Q Okay. I just want to make sure you
23 have that in front of you.
24 First of all, though, to touch on

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1 something that you were just asked by plaintiffs'
2 counsel, do you remember being asked earlier
3 today about some specific language in the 1978
4 IARC monograph?
5 A Yes.
6 Q Do you remember being asked about some
7 specific statements in that document on the
8 potential carcinogenicity and toxicity of NDMA
9 and NDEA?
10 A Yes.
11 Q And I just want to clarify. For
12 purposes of your report that you've provided in
13 this case, were you asked to provide any opinions
14 on the carcinogenicity or toxicity of NDMA or
15 NDEA?
16 A No.
17 Q Do you have any independent opinions on
18 whether NDMA or NDEA are a probable human
19 carcinogen or not?
20 A No. I'm not...
21 Q You're not here to opine --
22 A I'm not here to opine on that.
23 Q Would you defer to a toxicologist on
24 any of those questions?

<p style="text-align: right;">Page 322</p> <p>1 A Yes.</p> <p>2 Q You were also asked some questions</p> <p>3 about the daily acceptable intake limits that are</p> <p>4 currently in place by the FDA for NDMA and NDEA.</p> <p>5 Do you recall that?</p> <p>6 A Yes.</p> <p>7 Q Are you offering any opinions today or</p> <p>8 in your report about whether those levels are</p> <p>9 appropriate?</p> <p>10 A No.</p> <p>11 Q Do you have any opinions or are you</p> <p>12 intending to offer any opinions about --</p> <p>13 whatsoever on those levels or how they were</p> <p>14 calculated?</p> <p>15 A No.</p> <p>16 Q There was a discussion earlier on about</p> <p>17 a recent case where you served as an expert</p> <p>18 witness and some of your testimony was limited.</p> <p>19 Do you recall that?</p> <p>20 A I do recall that.</p> <p>21 Q That's the case where just last week</p> <p>22 you testified as an expert witness; right?</p> <p>23 A Yes, just last week.</p> <p>24 Q What's your understanding of the basis</p>	<p style="text-align: right;">Page 324</p> <p>1 A Yeah. That it was a legal issue as to</p> <p>2 whether or not it should be admitted and</p> <p>3 relevant.</p> <p>4 Q Did the limitation, to your</p> <p>5 understanding, have anything to do with the</p> <p>6 scientific analysis that you performed?</p> <p>7 A It did not have anything to do with</p> <p>8 scientific relevance.</p> <p>9 Q So here --</p> <p>10 And, actually, we're gonna finally turn</p> <p>11 to the opinions that you provided in the expert</p> <p>12 report that you prepared, and specifically</p> <p>13 looking at the corrected expert report that I</p> <p>14 believe you have a hard copy of in front of you</p> <p>15 and can refer to a specific exhibit in the</p> <p>16 folder, but I just want to confirm which that is.</p> <p>17 One second. I just want to make sure it's --</p> <p>18 So this will be Exhibit 4, previously</p> <p>19 introduced in the electronic Dropbox.</p> <p>20 Do you have a hard copy of this report</p> <p>21 in front of you, Dr. Baertschi?</p> <p>22 A I do.</p> <p>23 Q Turning to the conclusions section,</p> <p>24 subheading 6, and starting with paragraph 36,</p>
<p style="text-align: right;">Page 323</p> <p>1 for the limitation of your testimony in that</p> <p>2 case?</p> <p>3 MS. BOGDAN:</p> <p>4 Objection. Calls for a legal</p> <p>5 conclusion.</p> <p>6 MR. HARKINS:</p> <p>7 Q You can answer.</p> <p>8 A There was a -- a legal relevance</p> <p>9 dispute between the two sides and that relevance</p> <p>10 of some of the content in one of my expert</p> <p>11 reports. And the judge was asked to rule on it</p> <p>12 by the other counsel, and she ruled in favor of</p> <p>13 the other counsel, which then she said I'm</p> <p>14 forbidden or restricted from testifying as to the</p> <p>15 content around that particular issue as to the</p> <p>16 legal -- legal relevance of the -- of the data at</p> <p>17 issue.</p> <p>18 MR. HARKINS:</p> <p>19 Q And, just to clarify, you don't have a</p> <p>20 legal opinion on that ruling or that decision;</p> <p>21 right?</p> <p>22 A No.</p> <p>23 Q That's just your lay understanding of</p> <p>24 why your opinion was limited?</p>	<p style="text-align: right;">Page 325</p> <p>1 just for the benefit so that we actually can talk</p> <p>2 about this today, can you please summarize for</p> <p>3 maybe a potential jury the opinions and</p> <p>4 conclusions that you provided in your report?</p> <p>5 A Yes.</p> <p>6 I had opinions that can be lumped into</p> <p>7 three main areas, the first one being that it's</p> <p>8 inherently difficult to analyze low levels such</p> <p>9 as ND- -- such as the NDMA and NDEA found in</p> <p>10 valsartan medication- -- medications and that the</p> <p>11 identification of those structures and the</p> <p>12 quantification, when you combine those two, of</p> <p>13 these impurities requires specialized analytical</p> <p>14 testing methods that are well outside the scope</p> <p>15 of standard impurities testing and screening for</p> <p>16 impurities generally and for mutagenic</p> <p>17 carcinogenic impurities specifically.</p> <p>18 And those levels, more specifically,</p> <p>19 are thousands of times smaller than would be seen</p> <p>20 in valsartan time -- that would be seen in</p> <p>21 valsartan products here, and they -- thousands of</p> <p>22 time or hundreds of times lower than would be</p> <p>23 identified by ordinary or detected by ordinary</p> <p>24 methods for impurities.</p>

<p style="text-align: right;">Page 326</p> <p>1 And I -- I describe in that how many 2 times less, how much more sensitive screening you 3 would need, and -- and I say that the trace 4 levels of NDMA and NDEA impurities as defined by 5 the limits recommended by FDA would be 333 times 6 and 1220 times too low to be detected by these 7 methods for NDMA and NDEA, respectively. So -- 8 Q Would that be the first sort of main 9 focus of your report? 10 A Yeah. So the first main focus can be 11 summarized it's inherently difficult to analyze 12 for low levels of impurities such as these levels 13 that we're talking about. And then I detail -- I 14 detail about that more. 15 The second main area is that drug 16 manufacturers do not and cannot test for every 17 conceivable impurity or every conceivable 18 alerting structure that might be out there. 19 There is a wide variety and a huge number of 20 classes of potential mutagenic, carcinogenic 21 impurities that would make specialized testing 22 for impurities at the trace levels to detect all 23 of those or to be able to detect all of tho- -- 24 all of those impractical -- or impossible from a</p>	<p style="text-align: right;">Page 328</p> <p>1 that Teva had on hand at any particular site. Is 2 that right? 3 A That's correct. 4 Q You didn't inquire at all about 5 whether -- where any of the testing 6 instrumentation was located; right? 7 A Correct. 8 Q Why not? 9 A Because I didn't think it was relevant 10 to the issue at hand. It's not the presence of 11 specialized instrumentation, a mass spectrometer 12 or -- or a GC/MS. It's whether or not you have a 13 reason to go into doing specialized testing in 14 order to look for, hunt or fish for a low-level 15 impurity. And without reason to do that, you do 16 not do -- you -- that does not occur in -- in any 17 drug manufacturer. 18 So just having the instrumentation is 19 not -- does not affect what -- what my opinion 20 was as to whether or not -- 21 And I -- I -- I assumed that they would 22 have, and I -- and I -- and I can just assume 23 that the manufacturer had relevant 24 instrumentation that would be capable of -- of</p>
<p style="text-align: right;">Page 327</p> <p>1 practical point of view. And, accordingly, 2 regulators do not routinely or expect or require 3 such testing as I described in my report. 4 Q And what's the third main opinion that 5 you provided? 6 A The third main opinion is that the 7 specification testing for valsartan medications 8 in place prior to July 2018 did not include 9 testing that was capable of detecting NDMA and 10 NDEA at the levels ultimately detected in the 11 products, the valsartan products, and that the 12 testing that Teva did was -- was appropriate and 13 reasonable as -- as it analyzed its finished-dose 14 products in connection with the process change 15 that ZHP implemented in 2014. 16 Q Thank you, Doctor. 17 You were also asked some questions 18 about the testing instrumentation that Teva had 19 on hand during the relevant time period. Do you 20 recall that? 21 A I do recall that. 22 Q And I believe you testified that you 23 did not specifically inquire or seek more 24 information about the testing instrumentation</p>	<p style="text-align: right;">Page 329</p> <p>1 being put together and used. 2 Q Is the difficulty of analyzing for 3 low-level impurities like those seen in the 4 valsartan medication here addressed pretty 5 extensively as part of the first bucket in 6 conclusions in your expert report? 7 A Yes. I think it's addressed pretty -- 8 pretty clearly and relevantly. 9 Q And, just to clarify, does possession 10 of testing equipment alone determine whether Teva 11 had the ability to detect NDMA or NDEA at the 12 levels seen in valsartan medication? 13 A No. Just having instrumentation 14 doesn't mean that you're -- you -- you can test 15 it. You have to implement that instrumentation. 16 You have to configure it. You have to develop a 17 method for the matrix involved, and you have to 18 know what you're looking for, and you have to 19 have motivation to look for something of that 20 level. It just doesn't happen spontaneously. 21 Q All right. Dr. Baertschi, as reflected 22 on your amended list of materials considered, you 23 have received and reviewed some additional 24 materials since January 12th, 2022, when you</p>

<p style="text-align: right;">Page 330</p> <p>1 submitted your expert report in this case; right?</p> <p>2 A Yes.</p> <p>3 Q What kinds of materials have you seen?</p> <p>4 A Some depositions from expert witnesses,</p> <p>5 maybe an expert report or two, and -- and some</p> <p>6 other documents that maybe weren't --</p> <p>7 I don't -- basically, those are the --</p> <p>8 those are the things that come to mind is there</p> <p>9 were some depositions and expert reports that</p> <p>10 weren't available or that I reviewed, again, more</p> <p>11 thoroughly, or for the first time more</p> <p>12 thoroughly.</p> <p>13 Q Did you review any materials, either</p> <p>14 the deposition transcript or the exhibits, for</p> <p>15 Tim Anderson's deposition?</p> <p>16 A Yes.</p> <p>17 Q Who is Tim Anderson, to your</p> <p>18 understanding?</p> <p>19 A I believe he's the CGMP witness for</p> <p>20 Teva, but I kind of don't exactly know. I don't</p> <p>21 know Tim Anderson. I know Roger Willings better</p> <p>22 than Tim Anderson.</p> <p>23 Q Was one of the exhibits to Tim</p> <p>24 Anderson's deposition that you reviewed in</p>	<p style="text-align: right;">Page 332</p> <p>1 was not on the document that you were shown</p> <p>2 today.</p> <p>3 A Yes. It's redacted, blacked out.</p> <p>4 Q Did that information provide</p> <p>5 additional -- did that unredacted document</p> <p>6 provide additional information about the chemical</p> <p>7 structure and otherwise inform your opinions</p> <p>8 about that document?</p> <p>9 A It certainly did.</p> <p>10 Q Regardless, do you have any -- is any</p> <p>11 portion of your expert report, your opinions,</p> <p>12 reliant on that document that you reviewed or the</p> <p>13 document that you were shown today by plaintiffs'</p> <p>14 counsel?</p> <p>15 A Not at all.</p> <p>16 Q You've reviewed a lot of documents,</p> <p>17 both since you submitted your expert report and</p> <p>18 preparing for your deposition today; right?</p> <p>19 A Yes.</p> <p>20 Q Have you seen anything during that</p> <p>21 preparation or during your deposition today that</p> <p>22 causes you to change any of the opinions set</p> <p>23 forth in your January 12th, 2022, expert report?</p> <p>24 A No.</p>
<p style="text-align: right;">Page 331</p> <p>1 preparation for your deposition a version of the</p> <p>2 ZHP internal document that you were shown at the</p> <p>3 end of plaintiffs' counsel's questioning today?</p> <p>4 A Yes.</p> <p>5 Q Did you review that in preparation for</p> <p>6 your deposition?</p> <p>7 A Yes.</p> <p>8 Q Was that document redacted differently,</p> <p>9 the version that was introduced at Tim Anderson's</p> <p>10 deposition and the version that you were shown by</p> <p>11 plaintiffs' counsel today?</p> <p>12 A Yes. I don't believe it was redacted</p> <p>13 at all.</p> <p>14 Q You were asked some questions by</p> <p>15 plaintiffs' counsel about whether, looking at the</p> <p>16 document that you were shown today, you had</p> <p>17 questions or wanted to obtain more information</p> <p>18 about that document. Do you recall that?</p> <p>19 A Yes, I do.</p> <p>20 Q Did the version that you reviewed that</p> <p>21 was introduced at Mr. Anderson's deposition</p> <p>22 contain additional information?</p> <p>23 A Yes, it did.</p> <p>24 Q And, just to clarify, that information</p>	<p style="text-align: right;">Page 333</p> <p>1 Q I have no further questions for you,</p> <p>2 Dr. Baertschi. Thank you very much. It's been a</p> <p>3 long day.</p> <p>4 Can we go off the record?</p> <p>5 MS. BOGDAN:</p> <p>6 I have two questions on redirect.</p> <p>7 MR. HARKINS:</p> <p>8 I'm gonna have to ask what the scope</p> <p>9 is, considering you have no time left.</p> <p>10 MS. BOGDAN:</p> <p>11 Well, first of all, your objections</p> <p>12 have taken a lot of time on the record. I have</p> <p>13 two questions left, and I would like to ask them,</p> <p>14 and they're within -- within the scope of what</p> <p>15 you just questioned him on.</p> <p>16 MR. HARKINS:</p> <p>17 Dr. Baertschi, do you have a couple</p> <p>18 more minutes?</p> <p>19 THE WITNESS:</p> <p>20 I do. I've already missed my flight.</p> <p>21 MR. HARKINS:</p> <p>22 Okay. We have time for two.</p> <p>23</p> <p>24</p>

<p>Page 334</p> <p>1 EXAMINATION</p> <p>2 BY MS. BOGDAN:</p> <p>3 Q What is your understanding of how your</p> <p>4 opinions contribute to the defense of the class</p> <p>5 case?</p> <p>6 MR. HARKINS:</p> <p>7 Object to form to the extent it calls</p> <p>8 for a legal conclusion.</p> <p>9 But you can answer.</p> <p>10 A I don't have a -- that's a puzzling</p> <p>11 question. I don't have an opinion. I don't</p> <p>12 understand. I don't have an opinion on how it</p> <p>13 affects the class certification. That's a legal</p> <p>14 process I don't really understand.</p> <p>15 MS. BOGDAN:</p> <p>16 Q And is it your testimony and opinion in</p> <p>17 this case that while Novartis found NDMA in</p> <p>18 valsartan API, Teva could not?</p> <p>19 MR. HARKINS:</p> <p>20 Object to form. Scope. Foundation.</p> <p>21 You can answer.</p> <p>22 A Yeah, can -- can you rephrase it?</p> <p>23 Because the beginning of that question had some</p> <p>24 qualifiers that I want to make sure I understand.</p> <p>Page 335</p>	<p>Page 336</p> <p>1 MS. BOGDAN:</p> <p>2 I don't have any further questions.</p> <p>3 MR. HARKINS:</p> <p>4 Can we go off the record?</p> <p>5 VIDEOGRAPHER:</p> <p>6 Off record, 6:57 p.m.</p> <p>7 (Deposition concluded at 6:57 p.m. EST)</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>
<p>1 MS. BOGDAN:</p> <p>2 Q Is it your opinion that while Novartis</p> <p>3 found NDMA in valsartan API, that Teva could not?</p> <p>4 MR. HARKINS:</p> <p>5 Object to form. Scope. Foundation.</p> <p>6 Clearly not within the scope of his expert report</p> <p>7 or my redirect, which actually did address</p> <p>8 questions that he's answered in his expert</p> <p>9 report.</p> <p>10 But, Dr. Baertschi, if you have a</p> <p>11 question -- if you have an answer.</p> <p>12 A When you say Teva could not, I would --</p> <p>13 I would not agree with that, that Teva could not.</p> <p>14 Novartis detected it before anybody else.</p> <p>15 Teva and nobody else detected it up to that</p> <p>16 point. And I -- I don't even know if they're</p> <p>17 relevant products but, you know, lots or</p> <p>18 materials. Just as a -- my understanding of the</p> <p>19 facts is that Novartis was the first of anybody</p> <p>20 in the world to detect NDMA in a valsartan</p> <p>21 product. I don't know that to be true, but it's</p> <p>22 my understanding.</p> <p>23 MR. HARKINS:</p> <p>24 Thank you.</p>	<p>Page 337</p> <p>1 C E R T I F I C A T E</p> <p>2</p> <p>3 I do hereby certify that the above and</p> <p>4 foregoing transcript of proceedings in the matter</p> <p>5 aforementioned was taken down by me in machine</p> <p>6 shorthand, and the questions and answers thereto</p> <p>7 were reduced to writing under my personal</p> <p>8 supervision, and that the foregoing represents a</p> <p>9 true and correct transcript of the proceedings</p> <p>10 given by said witness upon said hearing.</p> <p>11 I further certify that I am neither of</p> <p>12 counsel nor of kin to the parties to the action,</p> <p>13 nor am I in anywise interested in the result of</p> <p>14 said cause.</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19 LOIS ANNE ROBINSON, RPR, RMR</p> <p>20 REGISTERED DIPLOMATE REPORTER</p> <p>21 CERTIFIED REALTIME REPORTER</p> <p>22</p> <p>23</p> <p>24</p>

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Exhibit 215

REDACTED

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF NEW JERSEY

3 - - -

4 IN RE: VALSARTAN, LOSARTAN, :
5 AND IRBESARTAN PRODUCTS : MDL No. 2875
6 LIABILITY LITIGATION :

7 -----

8 THIS DOCUMENT APPLIES TO ALL : HON ROBERT B.
9 CASES : KUGLER

10 - - -

11 CONFIDENTIAL INFORMATION - SUBJECT TO
12 PROTECTIVE ORDER

13

14 MARCH 21, 2022

15

16 - - -

17

18 Remote Videotape Deposition,
19 taken via Zoom, of ERIC SHEININ, Ph.D.,
20 commencing at 9:35 a.m., on the above
21 date, before Amanda Maslynsky-Miller,
22 Realtime Reporter and Certified Court
23 Reporter in and for the State of New
24 Jersey.

25

26 - - -

27

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31

32

Page 2

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(It is hereby stipulated and agreed by and among counsel that sealing, filing and certification are waived; and that all objections, except as to the form of the question, will be reserved until the time of trial.)

- - -

VIDEO TECHNICIAN: Good morning. We are now on the record. My name is Chris Clee, I'm a videographer for Golkow Litigation Services. Today's date is March 21st, 2022, and the time is 9:35 a.m. Eastern Standard Time.

This remote video deposition is being held in the matter of valsartan, Losartan and Irbesartan Products Liability Litigation, MDL Number 2875. The deponent is Eric Sheinin.

All parties to this

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1 deposition are appearing remotely
2 and have agreed to the witness
3 being sworn in remotely.
4 Due to the nature of remote
5 reporting, please pause briefly
6 before speaking to ensure all
7 parties are heard.
8 Counsel will be noted on the
9 stenographic record. The court
10 reporter is Amanda Miller, who
11 will now swear in the witness.
12 - - -
13 ERIC SHEININ, Ph.D., after
14 having been duly sworn, was
15 examined and testified as follows:
16 - - -
17 EXAMINATION
18 - - -
19 BY MR. DAVIS:
20 Q. Good morning, Dr. Sheinin.
21 My name is John Davis, I'm at the law
22 firm of Slack Davis Sanger down here in
23 Austin, Texas.
24 How are you doing this

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1 morning?
2 A. Okay, John. I'm doing all
3 right, thank you. How are you?
4 Q. Good. Not too bad. We're
5 braving some tornado warnings and severe
6 hail threats here, so hopefully we'll
7 keep power throughout this entire thing.
8 A. Okay. Good.
9 Q. Well, let me start by asking
10 you, have you ever given testimony under
11 oath before?
12 A. Yes, I have.
13 Q. Okay. About how many times?
14 A. Five or six, I think.
15 Q. Would that have been in the
16 capacity of an expert witness each of
17 those times?
18 A. I guess so. One of the
19 times I was still at FDA, and I was --
20 what I was asked to talk about, it was a
21 device/drug combination. And I had to
22 talk about the -- one of the chemicals in
23 the -- in the device/drug combination.
24 And I guess -- I wasn't

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1 necessarily called an expert witness, but
2 I was doing it as part of my job at FDA.
3 Q. Okay. Would that have been
4 in a court proceeding or some kind of
5 regulatory --
6 A. It was a deposition.
7 Q. -- proceeding?
8 A. It was a deposition.
9 Q. Okay. The underlying sort
10 of proceeding that the deposition
11 occurred in, would that have been a court
12 case or some kind of regulatory action?
13 A. I think it was regulatory.
14 I don't believe it was in a court action.
15 Q. Do you recall what the
16 device/drug combo was?
17 A. I'm not sure that I'm at
18 liberty to say.
19 Q. And then the other -- I
20 think you said five to six times total,
21 once in this FDA proceeding.
22 The other -- each of the
23 other times would have been as an expert
24 witness?

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1 A. Yes.
2 Q. Can you tell me what those
3 instances of you serving as an expert
4 witness in litigation, minus the FDA
5 proceeding, related to?
6 A. I can tell you that one of
7 them involved a court case in Canada
8 where I -- I did not give a deposition,
9 but I did appear at trial. And that
10 involved how FDA would look at a pure
11 enantiomer, if the original application
12 was for a racemate, what would be
13 expected from the chemistry perspective.
14 MR. REEFER: John is an
15 expert on that subject, aren't
16 you, John?
17 BY MR. DAVIS:
18 Q. I think I'm going to defer
19 to you on all those chemistry terms and
20 just say, that was a -- mostly a
21 scientific-based expert opinion as a
22 process chemist?
23 A. Not as a process chemist,
24 just as a review chemist and how -- how

<p>Page 14</p> <p>1 FDA would -- what FDA would want in the 2 application if it was a single enantiomer 3 versus what was -- what was already 4 approved as a racemate. 5 Q. Okay. 6 A. It didn't have anything to 7 do with the process. 8 Q. Well, sure. I guess let 9 me -- 10 A. The regulatory process. Let 11 me say that, yeah. 12 Q. Right. And that was going 13 to be my question. 14 The opinion you gave in that 15 was -- was a chemistry-related opinion, 16 not anything really focused on regulatory 17 affairs or anything like that, right? 18 A. Correct. 19 Q. Okay. 20 MR. REEFER: Eric -- can I 21 interject just to help us all out? 22 Eric, if you could give a 23 second-or-two pause before 24 answering, that would be helpful</p> <p>Page 15</p> <p>1 for everybody involved, okay? 2 THE WITNESS: Okay. 3 BY MR. DAVIS: 4 Q. Okay. So I think you 5 mentioned there might be a couple of 6 other times you served as an expert 7 witness. 8 Can you give me a brief 9 description of those instances as well? 10 A. One that I'll -- I should 11 wait. 12 One that I recall was -- it 13 involved a company that received approval 14 for an ANDA, and there was basically a 15 Phase IV commitment that FDA wanted them 16 to do, and there was also litigation that 17 caused the approval to be delayed because 18 of the litigation. 19 And what I testified to 20 involved a timeline that the company, for 21 whatever reason, delayed doing the work 22 that FDA wanted because they knew there 23 was a litigation and they would not be 24 able to launch the product until a</p>	<p>Page 16</p> <p>1 certain point in time. And so they 2 basically took their time responding to 3 FDA. 4 And my part of the -- what I 5 was asked to opine on was what if the 6 company had gone forward and done the 7 work immediately, what would FDA -- how 8 would FDA have looked at the final 9 approval, whether it would have speeded 10 up the -- getting the approval, which, of 11 course, would have been -- the company 12 would have been able to launch sooner. 13 So it was basically 14 something like that. 15 Q. And so that, the litigation, 16 underlying litigation, would have been a 17 patent litigation, I suppose? 18 A. Pardon me? 19 Q. Was this an instance of what 20 we call delayed generic entry litigation? 21 MR. REEFER: Object to form. 22 Go ahead, if you can. 23 THE WITNESS: I don't know 24 what that -- what that means. But</p> <p>Page 17</p> <p>1 the litigation ended sooner than 2 the company expected, so they 3 could have presumably launched 4 sooner if they had done the work 5 sooner. 6 BY MR. DAVIS: 7 Q. Who did you represent in 8 that case -- or, sorry, and by 9 "represent," I mean on whose behalf did 10 you submit an expert report? 11 A. You know, I don't recall 12 which company it was. 13 Q. Was it a follow-on generic 14 company, like, not the first-file ANDA 15 but a follow-on generic company? 16 A. I believe it was a first 17 generic. 18 Q. That company wasn't Mylan, 19 was it? 20 A. No. 21 Q. Do you know if it was any of 22 the manufacturer defendants in this 23 valsartan MDL litigation? 24 A. It was not.</p>
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<p style="text-align: right;">Page 18</p> <p>1 Q. Okay. Any other instances 2 of serving as an expert witness? 3 A. Yeah. I recall one, 4 actually, it was a functional food. And 5 my part involved evaluating work that the 6 other side's contract lab had performed, 7 trying to quantify the amount of an 8 impurity that was in the functional food 9 ingredient. 10 Q. Okay. Any other instances? 11 A. I believe -- I know there 12 were a couple of others. I can't recall 13 what the specifics were, but it involved 14 chemistry. 15 Q. What about a Fresenius 16 dialysis product? Did you ever give 17 expert testimony in that -- for Fresenius 18 in that case? 19 A. I don't believe I ever did 20 anything for Fresenius. 21 Q. Okay. You don't recall a 22 litigation versus Fresenius in the 23 Northern District of Illinois, Case 24 Number 16-cv-651?</p>	<p style="text-align: right;">Page 20</p> <p>1 A. I'm not sure all the -- 2 represent -- how it all came about. 3 But it's, basically, I'm 4 doing work through NDA Partners. And NDA 5 Partners has merged a couple of times. 6 So I still look at everything I'm doing 7 as through NDA Partners. So I guess 8 ProPharma is maybe now the parent. 9 Q. Does either ProPharma or NDA 10 Partners take a cut of your expert 11 witness fees? 12 A. Yes, they do. 13 Q. What is that percentage? 14 A. I don't know what the 15 percentage is, but I get \$400 an hour. 16 Q. Okay. Just to get a little 17 background on you, Dr. Sheinin, can you 18 give me a brief rundown of your 19 professional career as relates to FDA, 20 USP, and then your work in the consulting 21 industry? 22 A. Sure. I received a Ph.D. 23 from the University of Illinois, College 24 of Pharmacy, in organic chemistry in</p>
<p style="text-align: right;">Page 19</p> <p>1 A. I don't recall. I know I 2 did do a deposition on a case in Chicago, 3 so it might be related to that. But I 4 don't -- I don't recall that -- that I 5 was involved with Fresenius. 6 Q. In each of those instances 7 of serving as an expert witness, were 8 your reports and opinions tendered on 9 behalf of pharmaceutical manufacturers or 10 device manufacturers in each of those 11 instances, aside from the FDA one? 12 A. Pharmaceutical 13 manufacturers. 14 Q. When were you engaged by 15 Mylan for this case? 16 A. I believe it was late 2021. 17 Q. By "late 2021," can you give 18 a month? 19 A. November or December. 20 Q. I noticed on a couple of 21 your invoices that the invoices were 22 submitted from an entity called ProPharma 23 Group. 24 Who are they?</p>	<p style="text-align: right;">Page 21</p> <p>1 1971. 2 And I worked for FDA 3 beginning in February of 1971, in the 4 division of drug chemistry. I was a 5 research chemist. I was doing work on 6 nuclear magnetic resonance to identify 7 unknown samples and to develop analytical 8 methods to quantify the content of 9 pharmaceutical products. 10 Within a couple of years of 11 joining FDA, we bought our first mass 12 spectrometer on the drug side, and I 13 helped to run that instrument along with 14 another chemist who had come from a 15 different agency who was a mass 16 spectrometrists. 17 And between the two of us, 18 we published a number of papers, both 19 using NMR and using mass spec. We were 20 able to couple a gas chromatograph to the 21 mass spectrometer, and we did do research 22 and -- trying to identify unknown 23 materials that FDA field labs were not 24 able to handle.</p>

Page 22	Page 24
<p>1 Around 1978 or so, we had 2 four branches in the division of drug 3 chemistry. And one of the branch chiefs 4 passed away. I competed for that 5 position and was selected to become a 6 branch chief.</p> <p>7 And during that -- my time 8 in that position, I was responsible for 9 supervising a group of chemists who, 10 quote/unquote, performed method 11 validation for analytical methods that 12 companies had submitted in their new drug 13 applications to make sure that a 14 competent FDA analyst could run the 15 procedures and come up with results that 16 were comparable to what the company had 17 provided.</p> <p>18 We also had somebody in my 19 group who was doing powder -- x-ray 20 powder diffraction studies.</p> <p>21 Around 1985 or so, FDA 22 merged the Bureau of Drugs and the Bureau 23 of Biologics. They were called bureaus 24 in those days. And biologics was in</p>	<p>1 for all the drugs within the division. 2 So I took over the oncology drugs and the 3 radiopharmaceuticals, which included 4 other imaging agents as well.</p> <p>5 The bureau -- well, this was 6 now, then, the Center of Drug Evaluation 7 and Research. And there was a 8 reorganization that took place, and what 9 was created was the Office of 10 Pharmaceutical Science.</p> <p>11 And within the Office of 12 Pharmaceutical Science, there were four 13 smaller offices. One was the Office of 14 New Drug Chemistry. And I competed for 15 one of the three branches -- or one of 16 the three divisions within that office. 17 The Office of New Drug Chemistry had 18 three divisions. And I was selected as 19 one of the division directors, the 20 Division of New Drug Chemistry 3.</p> <p>21 And within that office, 22 then, Roger Williams, who was the head of 23 the office of -- Office of Pharmaceutical 24 Science, was also acting as director of</p>
Page 23	Page 25
<p>1 charge of the combined bureau, and they 2 made the decision, at one point in time, 3 to move some people to the review area, 4 chemists to the review area, because 5 there was a big backlog of new drug 6 applications that were pending chemistry 7 review.</p> <p>8 And as it turned out, they 9 closed the entire division of drug 10 chemistry and offered everybody in the 11 division a position in headquarters. And 12 some people took the position, some 13 people retired, and some people took 14 other positions within the government.</p> <p>15 I moved to the review area 16 as a supervisory chemist, and I had 17 responsibility, initially, for chemists 18 who were reviewing anti-inflammatory drug 19 applications on the new-drug side. This 20 was in the division of oncology and 21 radiopharmaceuticals.</p> <p>22 It was the first division 23 that had two supervisory chemists, and 24 eventually the responsibility ended up</p>	<p>1 the Office of New Drug Chemistry.</p> <p>2 The three division 3 directors -- as I mentioned, there were 4 three divisions. The three of us 5 competed for the permanent position of 6 director of the Office of New Drug 7 Chemistry, along with approximately 8 80-some people from the outside.</p> <p>9 I was selected to lead the 10 division of -- the Office of New Drug 11 Chemistry. And I worked in that position 12 for approximately two years, and then I 13 moved up to be the deputy director in the 14 Office of Pharmaceutical Science, which 15 was what was termed a super office versus 16 the smaller offices. I stayed in that 17 position for approximately one year.</p> <p>18 When I reached 30 years at 19 FDA, I was able to retire with a full -- 20 a full pension, and I decided to move to 21 USP.</p> <p>22 My boss at FDA, Roger 23 Williams, had left the year prior to my 24 retirement, and he went to USP as the</p>

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<p>1 chief executive officer, executive vice 2 president. And he recruited me to move 3 to USP as a vice president. 4 And I had responsibility for 5 the scientists at USP who were 6 responsible for creating content of USP 7 and NF, working with expert -- volunteers 8 on expert committees as well as the 9 pharmaceutical industry and, at times, 10 academia. 11 USP had a program to verify 12 the quality of dietary supplement 13 ingredients, and eventually they moved 14 into dietary supplement products. And 15 Roger Williams wanted to start a program 16 to evaluate the quality of active 17 pharmaceutical ingredients or drug 18 substances. 19 And I moved to that area, 20 and I worked on trying to recruit 21 companies to submit their DMFs or just 22 their procedures for their drug 23 substances. 24 And after working for about</p>	<p>1 any of the other defense experts who have 2 submitted opinions in this litigation? 3 A. I have not. 4 Q. You mentioned a -- and so 5 just a clarification on a few dates. 6 I think you said you retired 7 from FDA after 30 years, but you didn't 8 give a date. I assumed that means 2001, 9 if you started in 1971? 10 A. Yes. The end of February 11 2000 -- 2001. 12 Q. Okay. And then when did 13 you -- so you went to USP in 2001 as 14 well? 15 A. Yes. March of 2001. I 16 think I had two weeks -- 17 Q. And then -- 18 A. -- two weeks in between. 19 Q. Got you. 20 And then you retired from 21 USP around 2007-ish? 22 A. Yes. 23 Q. You mentioned trying to 24 recruit companies to submit their DMFs or</p>
Page 27	Page 29
<p>1 a year on that side, I felt, if I was 2 ever going to go into consulting, which 3 was something I had thought about when I 4 retired from FDA, that now was the time, 5 I was still young enough. And I went 6 into consulting. 7 And that's kind of a 8 nutshell of what my career has been. 9 I've been consulting since March of 2007. 10 Q. Okay. Thank you for that. 11 And I'll take a few questions just in 12 order. 13 You mentioned Roger 14 Williams, who was your former boss at 15 FDA, right? 16 A. Yes. 17 Q. Are you aware that he's 18 submitted an expert report in this case? 19 A. I'm not aware. 20 Q. So you would not have talked 21 to him or e-mailed with him about that at 22 all? 23 A. No, I have not. 24 Q. Have you communicated with</p>	<p>1 drug substance manufacturing procedures 2 to USP. 3 Would that be for 4 pharmaceutical drugs, or was that in the 5 context of dietary supplements? 6 A. No, this was pharmaceutical 7 ingredients. For the most part, 8 companies were reluctant to get into it 9 because FDA was the legal authority. 10 There was a -- the European 11 Pharmacopoeia, through the European 12 Directorate for the Quality of Medicines, 13 had a program that actually was required, 14 through EMA, to -- for companies to 15 submit their active ingredients for 16 evaluation. 17 And I believe Roger was 18 interested in getting into the same type 19 of -- same type of program. But I don't 20 believe that FDA would ever have given up 21 the responsibility for evaluating the 22 chemistry of the -- of active 23 pharmaceutical ingredients or drug 24 substances.</p>

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1 Q. In your consulting work
2 since 2007, have you -- have you always
3 consulted for industry?
4 MR. REEFER: Object to form.
5 THE WITNESS: I have given
6 some advice, a couple of times, to
7 academia. And I also did some
8 training for USP. I did some
9 training courses that USP offered.
10 BY MR. DAVIS:
11 Q. What percentage would you
12 say, of your consulting work since 2007,
13 has been for industry?
14 A. Probably 98 percent or more.
15 MR. DAVIS: I'm going to
16 mark your report, Dr. Sheinin.
17 That's Tab 1, Jason, in the
18 box, if he doesn't have a copy.
19 MR. REEFER: John, I'm going
20 to stand up, and I'm going to be
21 off camera for a moment.
22 MR. DAVIS: Sure.
23 MR. REEFER: Actually, just
24 give me one second, okay?

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1 For purposes of formality,
2 John, you see me now?
3 MR. DAVIS: Yes.
4 MR. REEFER: I just wanted
5 you to see that we have not yet
6 opened the box. So just give me
7 one moment, okay? I have
8 scissors.
9 MR. DAVIS: Not a problem.
10 MR. REEFER: Tape must have
11 been on sale at Costco when you
12 packaged this.
13 Tab 1, John?
14 MR. DAVIS: Tab 1.
15 - - -
16 (Whereupon, Exhibit
17 Sheinin-1, No Bates, Expert Report
18 of Eric Sheinin, Ph.D., was marked
19 for identification.)
20 - - -
21 BY MR. DAVIS:
22 Q. Dr. Sheinin, do you
23 recognize what's been handed to you as
24 Exhibit-1 -- that I've now marked as

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1 Exhibit-1 as your expert report in this
2 case?
3 A. Yes.
4 Q. In coming up with your
5 expert report, did you review at all
6 Federal Rule of Civil Procedure 26, which
7 governs the disclosure of expert reports
8 in federal court litigation?
9 A. No, I have never seen that.
10 Q. Well, I'll just tell you
11 that that rule states that, and I'm
12 quoting, The report must contain a
13 complete statement of all opinions the
14 witness will express and the basis and
15 reasons for them.
16 Did you -- did you hear that
17 sentence well?
18 A. Yes.
19 Q. Okay. Do you feel that your
20 expert report that you've submitted in
21 this case complies with what that rule
22 requires, namely, a complete statement of
23 all your opinions and the basis and
24 reasons for them?

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1 MR. REEFER: Object to form.
2 Calls for a legal conclusion.
3 THE WITNESS: Yes.
4 BY MR. DAVIS:
5 Q. So, in other words, there's
6 no opinions in your -- that aren't in
7 your report that you would be seeking to
8 express in this litigation, correct?
9 MR. REEFER: Object to form.
10 THE WITNESS: Yes.
11 BY MR. DAVIS:
12 Q. "Yes" meaning that there are
13 no other opinions that you're trying to
14 assert in this litigation that you have
15 not put in your expert report?
16 MR. REEFER: Object to form.
17 THE WITNESS: That's
18 correct.
19 BY MR. DAVIS:
20 Q. Turn, if you would, to the
21 second page of your report at Paragraph
22 8.
23 You state there, I offer the
24 opinions set forth in this report to a

<p>Page 34</p> <p>1 reasonable degree of scientific certainty 2 based on my education, experience, 3 training, expertise and referenced 4 resources. 5 Do you see that? 6 A. Yes. 7 Q. I just want to get some 8 clarification of what you mean by 9 "referenced resources." 10 What are you referring to 11 there? 12 A. I actually copied this 13 beginning from another expert report, and 14 I did not think about what referenced 15 resources I was -- what referenced 16 resources this referred to. 17 But I would assume it would 18 be things like the USP, the NF, FDA 19 guidances, ICH guidances, documents like 20 that. 21 Q. Did you write this report 22 with a degree of care, Dr. Sheinin? 23 A. Yes. 24 MR. REEFER: Object to form.</p> <p>Page 35</p> <p>1 THE WITNESS: A lot of care. 2 BY MR. DAVIS: 3 Q. But what you're telling me 4 is that you're not sure what you mean by 5 "referenced resources" there because you 6 copied it from another expert report of 7 yours? 8 MR. REEFER: Object to form. 9 Mischaracterizes testimony. 10 THE WITNESS: I tried to 11 explain what I would consider 12 referenced resources. And I would 13 still say the same thing. 14 I would consider these 15 referenced resources things such 16 as USP, the NF, FDA guidances. I 17 might add FDA policies and 18 procedures, ICH guidances. 19 That -- to me, that's what 20 referenced resources would be. 21 BY MR. DAVIS: 22 Q. Okay. Well, referenced 23 resources means resources that are 24 referenced, right?</p>	<p>Page 36</p> <p>1 Are there any resources that 2 you relied on that aren't -- are not 3 referenced in your report somewhere, 4 either in a footnote or your materials 5 considered list, I believe which is 6 Exhibit B, as you state in Paragraph 7? 7 A. I don't believe there are 8 any others. 9 Q. So would I be correct in 10 making the assumption that if there's 11 something that's not referred to 12 somewhere in your report, that you didn't 13 consider it in coming to your opinions? 14 MR. REEFER: Object to form. 15 Mischaracterizes testimony. 16 THE WITNESS: Can you repeat 17 the question? 18 BY MR. DAVIS: 19 Q. Sure. 20 Would I be correct -- what 21 I'm trying to do, Dr. Sheinin, is sort 22 of, you know, capture the view of 23 everything you reviewed for your expert 24 report in this case. And normally that's</p> <p>Page 37</p> <p>1 through either footnoting it as citations 2 in the body of your report or discussing 3 it explicitly in your report or 4 referencing a list of materials that you 5 considered or looked at in the process of 6 writing it. 7 And so what I'm trying to do 8 is clarify whether what's in the report 9 is the complete -- you know, wherever it 10 is in your report, that that's a complete 11 list of everything you looked at in 12 writing your report. 13 Do you follow? 14 MR. REEFER: Object to form. 15 THE WITNESS: I follow. And 16 I believe that's the situation. 17 BY MR. DAVIS: 18 Q. I just referenced Paragraph 19 7. You write there that, A list of 20 materials provided for my consideration 21 is attached as Exhibit B. 22 Do you see that? 23 A. Yes. 24 Q. Were those materials</p>
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1 provided by counsel?
2 A. Yes.
3 Q. Did you ask for them
4 specifically or was it just a package
5 that was given to you?
6 A. I believe it was a package
7 that was given to me.
8 Q. Did you ask counsel or make
9 any inquiries as to whether there was
10 anything additional that you might want
11 to look at?
12 A. I don't recall asking for
13 other things.
14 Q. So you just trusted that
15 what was given to you by Mylan's counsel
16 was a complete picture of the relevant
17 information that you might want to look
18 at?
19 MR. REEFER: Object to form.
20 THE WITNESS: I was asked to
21 opine on how USP functions and
22 what drug master files are.
23 Anything that I looked at that
24 counsel provided was to get a

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1 background for the overall
2 picture.
3 But I used my background and
4 my expertise and experience at USP
5 and at FDA to create my report.
6 BY MR. DAVIS:
7 Q. Well, my question was
8 whether you trusted that what was given
9 to you was a complete picture, including
10 for those topical areas you just
11 referenced, such as USP and drug master
12 files.
13 Is that --
14 MR. REEFER: Object to form.
15 Asked -- sorry, John.
16 BY MR. DAVIS:
17 Q. Did you trust that what was
18 given to you by Mylan's counsel painted a
19 complete and accurate picture for you?
20 MR. REEFER: Object to form.
21 Asked and answered.
22 THE WITNESS: What -- my
23 background, I believe, was
24 sufficient for me to give my

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1 opinion on USP and FDA's
2 consideration of drug master
3 files.
4 Anything that I looked at
5 that counsel had provided, as I
6 mentioned, was to provide a
7 background understanding of --
8 basic understanding of the issue.
9 It was nothing that I considered
10 in -- that I would have
11 incorporated into my report.
12 I would have to venture to
13 say that I would -- I would think
14 that the amount of material that I
15 received from counsel is a very,
16 very, very small proportion of the
17 documents that might have been
18 used to fully explain the
19 situation.
20 I just can't imagine that
21 if -- if counsel had provided me
22 everything that is included in the
23 court proceedings, it probably
24 would have more than filled up my

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1 office.
2 So I just don't understand
3 what -- what the question is
4 getting at.
5 BY MR. DAVIS:
6 Q. Well, sure, let me ask it, I
7 suppose, in a different way, then, which
8 is, did you -- upon receiving the
9 information that is listed at Exhibit B
10 of your report, upon reviewing that, did
11 you ever go back to counsel and ask for
12 anything else?
13 A. I'm turning the page.
14 Actually, I may have asked
15 for the response -- Mylan's response to
16 the warning letter. I can't recall for
17 definite whether that was included in the
18 original group.
19 Q. Did you ask -- sorry. Go
20 ahead, Dr. Sheinin. I didn't mean to cut
21 you off there.
22 A. I think I may have asked for
23 that response to the warning letter.
24 Q. Why would you have asked for

<p style="text-align: right;">Page 42</p> <p>1 that?</p> <p>2 A. Just to get an overall</p> <p>3 picture of how Mylan responded.</p> <p>4 Q. And by "warning letter,"</p> <p>5 you're referring to the November 2019</p> <p>6 warning letter issued to Unit 8?</p> <p>7 A. Yes.</p> <p>8 Q. While we're discussing that,</p> <p>9 real fast, and we may come back to it,</p> <p>10 but what's your understanding of how the</p> <p>11 FDA received Mylan's response to the</p> <p>12 warning letter?</p> <p>13 MR. REEFER: Object to form.</p> <p>14 Beyond the scope. Lack of</p> <p>15 foundation.</p> <p>16 THE WITNESS: I am -- I</p> <p>17 can't say how FDA responded. I</p> <p>18 have not seen anything in writing</p> <p>19 from FDA about the response.</p> <p>20 But I do know that Mylan --</p> <p>21 Mylan's valsartan products are</p> <p>22 back on the market, so I would</p> <p>23 have to assume that the -- that</p> <p>24 FDA was satisfied with their</p>	<p style="text-align: right;">Page 44</p> <p>1 response.</p> <p>2 It doesn't form the basis</p> <p>3 for anything that's in my report.</p> <p>4 BY MR. DAVIS:</p> <p>5 Q. Did you ask counsel to see a</p> <p>6 copy of the FDA's close-out letter for</p> <p>7 Mylan's warning letter?</p> <p>8 A. I don't believe I did.</p> <p>9 Q. Do you know if one exists?</p> <p>10 A. I do not know.</p> <p>11 Q. So you wouldn't know if that</p> <p>12 warning letter remains unresolved to this</p> <p>13 day?</p> <p>14 MR. REEFER: Object to form.</p> <p>15 Beyond the scope. Lack of</p> <p>16 foundation.</p> <p>17 THE WITNESS: I have no way</p> <p>18 of knowing whether it still exists</p> <p>19 or not.</p> <p>20 BY MR. DAVIS:</p> <p>21 Q. Okay. And you mentioned</p> <p>22 Mylan having a -- bringing valsartan back</p> <p>23 to the market, correct?</p> <p>24 A. As far as I know,</p>
<p style="text-align: right;">Page 43</p> <p>1 response, and that's how -- that's</p> <p>2 why the products are on the market</p> <p>3 again.</p> <p>4 BY MR. DAVIS:</p> <p>5 Q. Well, do you understand that</p> <p>6 the warning letter had to do, for Unit 8,</p> <p>7 in part, with Mylan's practices around</p> <p>8 recovered solvents and --</p> <p>9 MR. REEFER: Object to form</p> <p>10 as beyond the scope.</p> <p>11 BY MR. DAVIS:</p> <p>12 Q. -- as well as the issue of</p> <p>13 the nitrosamine contamination in the</p> <p>14 first place?</p> <p>15 MR. REEFER: Object to form.</p> <p>16 Beyond the scope. Compound. And</p> <p>17 mischaracterizes the document.</p> <p>18 THE WITNESS: That is the --</p> <p>19 the response from Mylan to FDA is</p> <p>20 not the basis of my report.</p> <p>21 So I consider that to be --</p> <p>22 it was irrelevant as to whether --</p> <p>23 is irrelevant in terms of how FDA</p> <p>24 might have responded to Mylan's</p>	<p style="text-align: right;">Page 45</p> <p>1 valsartan -- Mylan's valsartan products</p> <p>2 are on the market.</p> <p>3 Q. Do you know if Mylan had to</p> <p>4 commit to the FDA not to use recovered</p> <p>5 solvents until they could ensure that</p> <p>6 they were safely used and that --</p> <p>7 MR. REEFER: Object to form.</p> <p>8 I'm sorry, John.</p> <p>9 BY MR. DAVIS:</p> <p>10 Q. Sorry. Let me start that</p> <p>11 question over, Dr. Sheinin.</p> <p>12 Do you know if -- let me</p> <p>13 break it down into bits.</p> <p>14 Do you know if Mylan's</p> <p>15 valsartan product that's back on the</p> <p>16 market today is manufactured using</p> <p>17 recovered solvents?</p> <p>18 MR. REEFER: Object to form.</p> <p>19 Beyond the scope. Lack of</p> <p>20 foundation.</p> <p>21 THE WITNESS: That's</p> <p>22 something I don't have knowledge</p> <p>23 of. It's -- again, it's not</p> <p>24 something that I used to create my</p>

<p style="text-align: right;">Page 46</p> <p>1 report. Whether or not they're 2 using recovered solvents, I can't 3 tell you that. I don't know. 4 BY MR. DAVIS: 5 Q. Okay. Do you know if Mylan 6 had to change the process chemistry of 7 its valsartan API to bring it back to the 8 market? 9 MR. REEFER: Object to form. 10 Beyond the scope. Lack of 11 foundation. 12 THE WITNESS: I'm not a 13 process chemist, so it's very hard 14 for me to answer that question. 15 It's a very specialized area. 16 I've never worked in the 17 pharmaceutical industry, never 18 worked in developing a process for 19 manufacturing of a drug substance. 20 And it's not something that I can 21 opine on. 22 BY MR. DAVIS: 23 Q. Okay. But you're not -- 24 you're not aware, for example, of whether</p>	<p style="text-align: right;">Page 48</p> <p>1 nothing. It's beyond my 2 expertise. 3 BY MR. DAVIS: 4 Q. Well, sure, and I'm only 5 asking this because you brought up the 6 fact that Mylan has a valsartan product 7 back on the market. 8 And my question is, are you 9 familiar at all with the circumstances by 10 which Mylan was able to bring a valsartan 11 product back to the market? 12 MR. REEFER: Same objection. 13 THE WITNESS: Again, I'm not 14 a process chemist. And it's just 15 beyond what my expertise is. I 16 did not use any of that type of 17 information to form the basis for 18 my report. 19 BY MR. DAVIS: 20 Q. Okay. So is the answer no, 21 you're not familiar with the 22 circumstances by which Mylan was able to 23 bring a valsartan product back to the 24 market?</p>
<p style="text-align: right;">Page 47</p> <p>1 Mylan had to remove its use of 2 triethylamine and substitute it with 3 sodium bicarbonate in an effort to avoid 4 NDEA or other nitrosamine contamination 5 in order to bring valsartan back to the 6 market? 7 MR. REEFER: Object to form. 8 Compound. Beyond the scope. Lack 9 of foundation. 10 THE WITNESS: Again, I'm not 11 a process chemist, and I would not 12 attempt to try to interpret or 13 understand what processes Mylan 14 used. 15 I did not consider whether 16 or not there was a change in the 17 manufacturing process to form the 18 basis for my report. And 19 that's -- I use my experience at 20 USP and at FDA to create the 21 report. 22 So it's beyond my 23 understanding of process 24 chemistry, which is essentially</p>	<p style="text-align: right;">Page 49</p> <p>1 A. It's -- I'm not a process 2 chemist, and understanding the -- what 3 would go into changing, if that's what 4 occurred, changing the manufacturing 5 procedures is not something that I'm 6 qualified to evaluate. 7 And I'm going to have to 8 stand on that, that it's nothing that I 9 used in my report. 10 Q. Well, my question isn't, you 11 know, calling for any kind of process 12 chemistry. I'm just asking what you 13 reviewed. 14 And my question is, did you 15 review any documents or anything related 16 to how Mylan was able to bring a 17 valsartan product back to the market? 18 A. My -- again, I'm not a 19 process chemist. So I -- as to what was 20 involved and how much work was involved, 21 I can't really opine on that. 22 Q. What about concessions to 23 the regulator, are you familiar with any 24 concessions Mylan had to make to the</p>

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<p>1 regulator, the FDA, in order to bring a 2 valsartan product back on the market? 3 MR. REEFER: Object to form. 4 Vague. Beyond the scope. Lack of 5 foundation. 6 THE WITNESS: I am -- I 7 am -- let me start over. 8 I am -- I don't know what -- 9 I'm not a process chemist, and I 10 just feel that whatever Mylan did 11 to get on the market is beyond 12 what I was asked to look at and 13 what I was asked to opine on. 14 I used my expertise and my 15 background at USP and FDA to 16 create my report. Anything else 17 was immaterial to providing my 18 opinions that are in my report. 19 BY MR. DAVIS: 20 Q. Okay. Well, let me ask it 21 this way, then: Is the fact that Mylan 22 is back on the market with a valsartan 23 product, under circumstances that you 24 don't know or understand, that's not</p>	<p>1 least the portions of the requirements in 2 the ANDA for the drug substance made 3 reference to the drug master file. 4 So there was very little 5 information in the ANDA itself, and I did 6 not pursue asking counsel to provide me 7 the DMF because I felt it was irrelevant 8 to what my part of the -- creating my 9 report was. 10 I was just -- the ANDAs were 11 there and I thought I probably ought to 12 take a look at them, but there was really 13 nothing for me to understand. And I just 14 said, I don't need that information to 15 create my report on how USP operates and 16 what a drug master file is. So I did not 17 pursue it. 18 Q. Well, that's my -- you kind 19 of touched on my next question, which is, 20 you told me your assignment was to opine 21 on USP and drug master files. 22 But you didn't think to ask 23 Mylan for the drug master file that's at 24 issue in this case?</p>
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<p>1 relevant to any of the opinions in your 2 report, is it? 3 A. I don't believe so. 4 Q. Okay. Thank you. 5 You list the ANDAs in 6 Exhibit B to your report, do you not? 7 A. Yes, I do list them. 8 Q. Do you understand that those 9 ANDA applications all made reference to a 10 drug master file? 11 A. Yes. 12 Q. Did you review the full drug 13 master file? 14 A. I didn't review any part of 15 the drug master file. 16 Q. Okay. So that was my 17 question. 18 So you reviewed the ANDA 19 applications but not the underlying drug 20 master file that those ANDAs made 21 reference to? 22 A. I glanced at one of the 23 ANDAs. I did not review all three of 24 them. And what I saw was mostly -- at</p>	<p>1 A. I did not because I was 2 giving, in my expert report, a general 3 overview of drug master files. I was not 4 asked to opine on the quality or the 5 content of Mylan's drug master file, so 6 it was irrelevant. 7 Q. Okay. That -- let me 8 clarify exactly what your assignment was 9 in this case, then, because it's nowhere 10 written in your report what your 11 assignment was. 12 And to be honest, I'm a 13 little confused, because you're telling 14 me your assignment was to opine on drug 15 master files generally but not to opine 16 on Mylan's drug master file in any way in 17 this case; is that right? 18 A. That's correct. I was not 19 asked to opine on the quality of Mylan's 20 drug master file. 21 Q. And you did not, in fact, 22 opine on the quality of Mylan's drug 23 master file in your report, did you? 24 A. I couldn't. Because, one, I</p>

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1 wasn't asked to; and, two, I never saw
2 the drug master file.
3 Q. So since it's written
4 nowhere in your report, can you tell me
5 exactly what your assignment was in this
6 case?
7 A. My assignment was to -- the
8 basic part of my assignment, the bulk of
9 it, was to talk about USP and the
10 background of USP, in terms of how USP is
11 organized, USP's recognition in the Food,
12 Drug and Cosmetic Act, and to give a
13 brief description, discussion of drug
14 master files and why -- why there are
15 drug master -- I talked about why there
16 are drug master files, types of drug
17 master files and so on.
18 I was also asked to comment
19 on Dr. Najafi's expert report.
20 Q. Were you asked to comment on
21 John Quick's expert report?
22 A. I was asked if I -- if I --
23 if I wanted to comment on John Quick's,
24 as well as Najafi, but I felt that

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1 Quick's was more involved with GMPs and,
2 that was not my area of expertise at FDA.
3 So commenting on Najafi was more in line
4 with the function of my report and the
5 expertise that I have.
6 Q. Okay.
7 MR. DAVIS: I'm going to
8 mark Tab 2 as Exhibit-2, Jason.
9 - - -
10 (Whereupon, Exhibit
11 Sheinin-2, No Bates, 1/12/22
12 Letter, Trischler to Counsel, was
13 marked for identification.)
14 - - -
15 MR. REEFER: Okay.
16 BY MR. DAVIS:
17 Q. Dr. Sheinin, this was a
18 letter from Jason's law firm that
19 accompanied the disclosure of your expert
20 report.
21 Do you understand that?
22 MR. REEFER: Object to form.
23 Why don't you start by asking if
24 he's seen it before?

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1 BY MR. DAVIS:
2 Q. Have you seen this letter
3 before?
4 A. I've not seen this letter
5 before, and I have never seen a letter
6 that looks like this.
7 Q. Well, yeah, let me just
8 represent to you, then, that this was a
9 letter from Jason's law firm that was
10 delivered to us accompanying your expert
11 report.
12 Do you see that your name is
13 referenced in there and it's addressed to
14 a number of plaintiffs' counsel in this
15 case?
16 MR. REEFER: Object to form.
17 Lack of foundation.
18 THE WITNESS: I see that my
19 name is on here, yes. And it's --
20 BY MR. DAVIS:
21 Q. Okay.
22 A. -- talking about my expert
23 report is also enclosed.
24 Q. If you look down at

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1 Paragraph 2, it says that your report is,
2 For purposes of rendering opinions as to
3 class certification issues and rebutting
4 the class certification opinions of the
5 class certification experts disclosed by
6 the plaintiffs' executive committee.
7 Do you see that?
8 A. I see it.
9 Q. Do you know what class
10 certification issues you address in your
11 report?
12 MR. REEFER: Object to form.
13 Beyond the scope. Calls for a
14 legal conclusion.
15 THE WITNESS: I don't know
16 what "class certification" means.
17 BY MR. DAVIS:
18 Q. And the second part of that
19 is to rebut the reports of the
20 plaintiffs' experts.
21 In your case, that's only
22 Dr. Najafi; is that right? Is that your
23 testimony?
24 MR. REEFER: Object to form.

<p>Page 58</p> <p>1 Mischaracterizes testimony. 2 THE WITNESS: I discuss 3 Dr. Najafi's report in my report, 4 yes. 5 BY MR. DAVIS: 6 Q. And there's no other 7 plaintiffs' expert report that you both 8 reviewed and intend to rebut in your 9 report, is there? 10 MR. REEFER: Object to form. 11 Foundation. 12 Go ahead, Doctor. 13 THE WITNESS: That's 14 correct. 15 BY MR. DAVIS: 16 Q. You mentioned, Dr. Sheinin, 17 that your educational background is that 18 you have a Ph.D. in organic chemistry; is 19 that right? 20 A. That's correct. 21 Q. Can you, at a very broad 22 level, speaking to a -- most certainly a 23 non-expert like me and Jason -- 24 MR. REEFER: That's right.</p> <p>Page 59</p> <p>1 BY MR. DAVIS: 2 Q. -- tell us -- tell us what 3 organic chemistry is? 4 A. Organic chemistry is, in the 5 briefest of statements, is the chemistry 6 of carbon compounds. That's probably the 7 easiest way to explain it. 8 There's different classes of 9 chemicals that are considered organic. 10 There's various functional groups. 11 I can't say 100 percent that 12 every organic chemical contains carbon, 13 but, for the most part, that's -- that's 14 true. And it's -- involves reactions 15 using other organic chemicals as well as 16 non-organic chemicals to manufacture or 17 synthesize a second organic chemical and 18 sometimes maybe a third and a fourth. 19 That's what my -- my Ph.D. 20 thesis involved synthesizing a number of 21 compounds that were subsequently sent to 22 the National Cancer Institute for testing 23 for activity against -- against cancer. 24 And, unfortunately, none of the chemicals</p>	<p>Page 60</p> <p>1 I manu -- I synthesized had any activity. 2 I always felt that I was 3 going to get a job working for somebody 4 who is doing organic chemistry. That 5 turned out not to be the case. When I 6 joined FDA, we had an organic chemist in 7 our group, and he actually worked as a 8 functioning organic chemist. I have 9 never worked as a functioning organic 10 chemist. 11 So it's -- I think it's 12 something that is fairly common, 13 certainly it is among people that I knew 14 who went to graduate school with me, they 15 don't necessarily end up working in what 16 your major was. 17 So I'm more of an analytical 18 chemist with knowledge of regulatory. 19 But I've never worked as an organic 20 chemist. 21 Q. Right. In fact, I think, 22 you know, in your brief FDA history you 23 gave me, your work with mass spec and 24 GC -- you know, coupling it with a GC in</p> <p>Page 61</p> <p>1 the early '70s, that's more analytical 2 chemistry, right? 3 A. Yes. 4 Q. So harkening back to your 5 dissertation thesis days when you 6 synthesized a few compounds with the 7 hopes that they might have an effect on 8 cancer, did you work in the lab at all 9 in, you know, synthesizing those -- 10 creating those chemical reactions to 11 synthesize those compounds? 12 A. Oh, yeah. I mean, that's 13 how I got the compounds. 14 Q. So in working with -- would 15 you have worked with, like, reagents, 16 catalysts, solvents, all that business, 17 in order to create those chemical 18 reactions that would ultimately yield the 19 compound you wanted to create? 20 MR. REEFER: Object to form. 21 THE WITNESS: Yes. I did 22 the synthesis myself. 23 BY MR. DAVIS: 24 Q. So how would you know, in</p>
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<p>Page 62</p> <p>1 doing that, what to avoid mixing together 2 to create a dangerous reaction? What 3 kind of materials would you look at, 4 aside from just your own educational 5 knowledge of how these substances 6 interact? 7 MR. REEFER: Object to form. 8 Beyond the scope. 9 THE WITNESS: I relied on my 10 advisor to give me advice on if 11 there was any danger or any 12 possible reactions that he 13 considered to be dangerous. 14 BY MR. DAVIS: 15 Q. Did you rely on any kind of 16 written materials in addition to just 17 what your advisor told you? 18 MR. REEFER: Object to form. 19 Beyond the scope. 20 THE WITNESS: You know, 21 that's over 50 years ago, and I 22 can't remember if there was 23 anything written or not. But I 24 relied on my advisor.</p> <p>Page 63</p> <p>1 BY MR. DAVIS: 2 Q. Okay. Do you know what an 3 MSDS is? 4 A. Yes, I do. 5 Q. Like a safety data sheet for 6 a particular substance? 7 A. Yes. 8 Q. Okay. Is that something 9 that -- would those have existed at that 10 timeframe? 11 A. As far as I can remember, I 12 don't believe there were safety data 13 sheets at that time. 14 Q. If you were doing that kind 15 of organic chemistry today, is that 16 something you might want to look at, the 17 safety data sheets or MSDS? 18 MR. REEFER: Objection. 19 Form. Incomplete hypothetical. 20 Beyond the scope. 21 THE WITNESS: I mean, if I 22 was doing organic chemistry today, 23 I would want to know if there was 24 any safety issues with the</p>	<p>Page 64</p> <p>1 materials that I'm working with. 2 It's something that did not exist 3 in those days. 4 BY MR. DAVIS: 5 Q. And if you were doing that 6 today, one of the most prominent 7 resources you could -- you could consult 8 would be the safety data sheet, or MSDS, 9 that accompanies whatever reagent or 10 catalyst it is that you're working with, 11 right? 12 MR. REEFER: Object to form. 13 Beyond the scope. Incomplete 14 hypothetical. 15 THE WITNESS: I would have 16 to assume that I would look at 17 those, at least once, for any 18 chemical that I work with. I 19 wouldn't have to keep going back 20 to look at them. 21 BY MR. DAVIS: 22 Q. Okay. 23 MR. REEFER: Hey, John, this 24 is Jason. I had a venti coffee</p> <p>Page 65</p> <p>1 this morning. We've been going 2 about an hour and 20 minutes. 3 Would you mind just taking a 4 five-minute bathroom break? 5 MR. DAVIS: Sure. Not a 6 problem. 7 Dr. Sheinin, do you need 8 five minutes or ten minutes? Up 9 to you. 10 We can go off the record, by 11 the way. 12 VIDEO TECHNICIAN: Going off 13 the record. The time is 14 10:50 a.m. 15 - - - 16 (Whereupon, a brief recess 17 was taken.) 18 - - - 19 VIDEO TECHNICIAN: We are 20 back on the record. The time is 21 11:00 a.m. 22 BY MR. DAVIS: 23 Q. Just one clean-up question, 24 Dr. Sheinin, before I move on.</p>
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<p style="text-align: right;">Page 66</p> <p>1 Do you recall telling me</p> <p>2 that you're not a CGMP expert?</p> <p>3 A. Yeah, I recall.</p> <p>4 Q. Okay. So would I take that</p> <p>5 to mean that you're not offering any</p> <p>6 opinion in this litigation that Mylan</p> <p>7 was, in fact, in compliance with CGMPs?</p> <p>8 A. I'm not offering an opinion</p> <p>9 directly on whether they're in compliance</p> <p>10 with GMPs. I know that their product is</p> <p>11 on the market. I know that FDA has</p> <p>12 inspected their facilities. And I know</p> <p>13 there was a warning letter, and I know</p> <p>14 that they're back on the market.</p> <p>15 That's pretty much beyond</p> <p>16 what I know about Mylan and their GMPs.</p> <p>17 Q. But just to clarify, you're</p> <p>18 not offering any kind of expert opinion</p> <p>19 in this litigation that Mylan was in</p> <p>20 compliance with CGMPs, despite stuff</p> <p>21 that's tangential to that that you've</p> <p>22 reviewed, correct?</p> <p>23 A. My expert report is</p> <p>24 discussing drug master files and USP. It</p>	<p style="text-align: right;">Page 68</p> <p>1 asking -- well, hang on, Jason,</p> <p>2 I'm not asking him to speculate.</p> <p>3 I'm just asking if he saw that</p> <p>4 statement in the letter that he</p> <p>5 reviewed.</p> <p>6 BY MR. DAVIS:</p> <p>7 Q. Do you recall seeing that</p> <p>8 statement in the letter that you -- in</p> <p>9 the warning letter, Dr. Sheinin?</p> <p>10 A. I recall the warning letter.</p> <p>11 Can you put it up on the screen?</p> <p>12 Q. Sure.</p> <p>13 A. So I can see the exact</p> <p>14 language. Or do we have it in our -- in</p> <p>15 our package?</p> <p>16 Q. Just a second, I'll bring it</p> <p>17 up.</p> <p>18 MR. REEFER: Do you have it</p> <p>19 as an exhibit, John?</p> <p>20 MR. DAVIS: Yes. That would</p> <p>21 be Tab 15.</p> <p>22 MR. REEFER: One moment,</p> <p>23 okay?</p> <p>24 MR. DAVIS: Yep.</p>
<p style="text-align: right;">Page 67</p> <p>1 does not discuss GMPs. I'm not a -- I'm</p> <p>2 not -- as I said and you agreed, I'm not</p> <p>3 an expert in GMPs, and I'm not offering</p> <p>4 to opine on it.</p> <p>5 Q. So, for example, you said</p> <p>6 you reviewed the FDA warning letter</p> <p>7 issued to Mylan Unit 8, which</p> <p>8 manufactured valsartan API; isn't that</p> <p>9 right?</p> <p>10 A. I looked at it. I wouldn't</p> <p>11 necessarily say -- I did not review it</p> <p>12 in depth. It was not something that I</p> <p>13 needed for forming my opinions in my</p> <p>14 expert report. But I did look at it.</p> <p>15 Q. Right. And would you have</p> <p>16 seen the statement at the beginning of</p> <p>17 that letter that the FDA observed CGMP</p> <p>18 deviations at that facility, which was</p> <p>19 the -- you know, the reason they were</p> <p>20 sending the warning letter?</p> <p>21 MR. REEFER: Object to the</p> <p>22 form. Calls for speculation.</p> <p>23 Go ahead --</p> <p>24 MR. DAVIS: Well, I'm not</p>	<p style="text-align: right;">Page 69</p> <p>1 - - -</p> <p>2 (Whereupon, Exhibit</p> <p>3 Sheinin-3, MYLAN-MDL2875-003457,</p> <p>4 11/5/19 FDA Warning Letter, was</p> <p>5 marked for identification.)</p> <p>6 - - -</p> <p>7 MR. DAVIS: I'm marking that</p> <p>8 as Exhibit-3.</p> <p>9 MR. REEFER: John, I'm not</p> <p>10 sure if there's a question</p> <p>11 pending. I'm sorry.</p> <p>12 MR. DAVIS: Sure.</p> <p>13 BY MR. DAVIS:</p> <p>14 Q. Do you have the letter in</p> <p>15 front of you, Dr. Sheinin?</p> <p>16 A. I do.</p> <p>17 Q. Do you recognize that to be</p> <p>18 a copy of the November 5th, 2019, Unit 8</p> <p>19 warning letter that you reference in</p> <p>20 Exhibit B to your report?</p> <p>21 A. Yes.</p> <p>22 Q. And do you see the third</p> <p>23 paragraph -- second and third paragraph</p> <p>24 down, This warning letter summarizes</p>

<p>Page 70</p> <p>1 significant deviations from CGMP for 2 APIs. And, Because your methods and 3 facilities and controls for manufacturing 4 processing, packing or holding do not 5 conform to CGMP, your API are 6 adulterated.</p> <p>7 Do you see those statements?</p> <p>8 A. I see them.</p> <p>9 Q. And because you're not 10 offering any kind of opinion that Mylan 11 was, in fact, in GMP compliance, you 12 don't take any issue with what the FDA 13 says here, do you?</p> <p>14 MR. REEFER: Object to form.</p> <p>15 Mischaracterizes testimony.</p> <p>16 THE WITNESS: This -- this 17 Paragraph 2 and Paragraph 3, I 18 would say probably Paragraph 4, 19 with different dates is pretty 20 much standard boilerplate language 21 that's in every warning letter.</p> <p>22 Mylan's valsartan product is 23 on the market, it's in conformance 24 with the requirements of the USP</p> <p>Page 71</p> <p>1 monograph for the API, as well as 2 for the tablets. And the fact 3 that this language is in here, 4 it's in every warning letter that 5 I've seen.</p> <p>6 BY MR. DAVIS:</p> <p>7 Q. Well, just like with your 8 report, Dr. Sheinin, you have some stock 9 language, for example, that we went over 10 this morning.</p> <p>11 It doesn't make it any less 12 true, right? It doesn't mean that the -- 13 just because it's in every FDA warning 14 letter doesn't mean that this one issued 15 to Mylan, the FDA doesn't mean it when 16 they say that Mylan was not in GMP 17 compliance at Unit 8, correct?</p> <p>18 A. This is -- again, it's 19 boilerplate language that's in every 20 letter, every warning letter. The fact 21 that FDA has allowed Mylan to come back 22 on the market, has not withheld anything 23 from Mylan, there are no import alerts 24 that -- over Mylan, and the fact that</p>	<p>Page 72</p> <p>1 this is -- again, like in my report, this 2 is boilerplate language. It's nothing 3 that forms the basis for my report.</p> <p>4 Q. So should I -- should I 5 give, for example, the boilerplate 6 language in your report less stock 7 somehow, or should I take that to 8 actually be language in your report?</p> <p>9 MR. REEFER: Object to form.</p> <p>10 Compound. Vague.</p> <p>11 THE WITNESS: You can -- you 12 can use that language in my report 13 in any way you like. It's --</p> <p>14 BY MR. DAVIS:</p> <p>15 Q. Well, I'm asking -- I'm 16 asking your opinion, Dr. Sheinin.</p> <p>17 Are you telling me that the 18 language that you cribbed from an old 19 report, I should put less stock into 20 simply because you --</p> <p>21 MR. REEFER: Object to form.</p> <p>22 BY MR. DAVIS:</p> <p>23 Q. -- simply because it's 24 boilerplate?</p> <p>Page 73</p> <p>1 MR. REEFER: Object to form.</p> <p>2 Argumentative. Mischaracterizes 3 the testimony.</p> <p>4 THE WITNESS: Again, 5 that's -- it's typical language. 6 It's -- and the boilerplate 7 language here is just boilerplate 8 language.</p> <p>9 It's -- the fact that FDA 10 let -- has let Mylan back on the 11 market says to me that whatever 12 deviations there were from current 13 good manufacturing practices are 14 such that FDA feels comfortable 15 with Mylan marketing the valsartan 16 products.</p> <p>17 BY MR. DAVIS:</p> <p>18 Q. But that's just pure 19 speculation on your part.</p> <p>20 You told me, Dr. Sheinin, 21 that you haven't looked at any follow-up 22 on this warning letter to see if it's 23 been closed out; and you told me you have 24 no idea what circumstances Mylan was</p>
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<p style="text-align: right;">Page 74</p> <p>1 allowed back on the market, right?</p> <p>2 MR. REEFER: Object to form.</p> <p>3 John, you asked him questions</p> <p>4 about this warning letter and now</p> <p>5 you're yelling at him for trying</p> <p>6 to answer them.</p> <p>7 MR. DAVIS: Well, no. He's</p> <p>8 told me, Jason, that he's not a</p> <p>9 CGMP expert. And I'm just trying</p> <p>10 to elucidate what he means by that</p> <p>11 with an example.</p> <p>12 And my example here --</p> <p>13 MR. REEFER: Right.</p> <p>14 MR. DAVIS: -- is in this</p> <p>15 warning letter that FDA issued to</p> <p>16 Mylan, the FDA says that there's</p> <p>17 significant CGMP deviations.</p> <p>18 BY MR. DAVIS:</p> <p>19 Q. My question to you,</p> <p>20 Dr. Sheinin, is, are you offering any</p> <p>21 opinion that Mylan, in fact, during this</p> <p>22 timeframe, was in CGMP compliance,</p> <p>23 contrary to what the FDA says in this</p> <p>24 warning letter?</p>	<p style="text-align: right;">Page 76</p> <p>1 Go ahead.</p> <p>2 A. But the first time I heard</p> <p>3 about any issues with nitrosamines was in</p> <p>4 2018.</p> <p>5 Q. Well, my question was</p> <p>6 actually the more basic one, which is</p> <p>7 when you first learned what a nitrosamine</p> <p>8 compound was, not whether there were any</p> <p>9 issues in medications.</p> <p>10 And it sounds like the</p> <p>11 answer is at some point in graduate</p> <p>12 school for organic chemistry?</p> <p>13 A. Yeah, I mean, I -- that's a</p> <p>14 functional group, and it's -- a</p> <p>15 nitrosamine, you have to have an amine,</p> <p>16 and it's -- so that's included in</p> <p>17 functional groups in organic chemistry.</p> <p>18 Q. Right.</p> <p>19 A. It's nothing that I worried</p> <p>20 about as a graduate student.</p> <p>21 Q. Right. You would have to</p> <p>22 have --</p> <p>23 A. It was just a functional</p> <p>24 group.</p>
<p style="text-align: right;">Page 75</p> <p>1 MR. REEFER: Object to form.</p> <p>2 Asked and answered.</p> <p>3 THE WITNESS: I'm not</p> <p>4 offering any opinion, because I'm</p> <p>5 not a GMP expert.</p> <p>6 BY MR. DAVIS:</p> <p>7 Q. Okay. Thank you. Thank</p> <p>8 you.</p> <p>9 When did you first learn</p> <p>10 anything about nitrosamines, Dr. Sheinin?</p> <p>11 A. I would have to say probably</p> <p>12 in 2018 when I heard about the reports of</p> <p>13 nitrosamines being in certain products,</p> <p>14 FDA announcements.</p> <p>15 I would think that's the</p> <p>16 first time that I heard -- well, I</p> <p>17 probably heard about them in graduate</p> <p>18 school, but that's -- that's neither here</p> <p>19 nor there.</p> <p>20 Q. Well, that's actually --</p> <p>21 A. I knew what a nitrosamine</p> <p>22 was.</p> <p>23 Q. Sorry, I didn't mean to cut</p> <p>24 you off there.</p>	<p style="text-align: right;">Page 77</p> <p>1 Q. Sorry.</p> <p>2 You would have to have an</p> <p>3 amine and a nitrosating agent under</p> <p>4 acidic conditions, right?</p> <p>5 A. That's nothing that I</p> <p>6 studied in graduate school. I knew what</p> <p>7 a nitrosamine was. I didn't know how</p> <p>8 they formed or what reactions it would</p> <p>9 take.</p> <p>10 Q. Do you know who Dr. Edwin</p> <p>11 Gump is at USP?</p> <p>12 A. The name is not familiar.</p> <p>13 I've been gone for over 15 years, so he</p> <p>14 must be new or --</p> <p>15 Q. If that --</p> <p>16 A. -- since I left.</p> <p>17 Q. Sorry.</p> <p>18 Well, he's stated that</p> <p>19 nitrosamines can be formed, quote, Very</p> <p>20 simply through really simple chemistries.</p> <p>21 Do you have any reason to</p> <p>22 disagree with that statement about how</p> <p>23 nitrosamines are formed?</p> <p>24 MR. REEFER: Object to form.</p>

<p style="text-align: right;">Page 78</p> <p>1 Beyond the scope. 2 THE WITNESS: I'd have to 3 see what document -- what's his 4 name, Gump, Dr. Gump that 5 you're -- 6 BY MR. DAVIS: 7 Q. Dr. Edwin Gump. 8 A. -- referring to? I'd want 9 to try to see his documents and evaluate 10 it for myself. 11 Q. Okay. 12 MR. DAVIS: Let's mark Tab 13 9, Jason, as Exhibit-4. 14 - - - 15 (Whereupon, Exhibit 16 Sheinin-4, No Bates, USP Announces 17 Approval of Chapter on 18 Nitrosamines Impurities, was 19 marked for identification.) 20 - - - 21 BY MR. DAVIS: 22 Q. And I apologize, 23 Dr. Sheinin, it appears that when I 24 printed this to PDF that part of the</p>	<p style="text-align: right;">Page 80</p> <p>1 Beyond the scope. 2 THE WITNESS: His statement 3 is nothing that I use in my report 4 to offer my opinion in this case. 5 I'm not sure that it's 6 really that simple. I would -- 7 well, I'm going to leave it at 8 that. It may be simple, it may 9 not be quite so simple. 10 BY MR. DAVIS: 11 Q. And in writing your report 12 in this case, did you refresh yourself on 13 the chemistry by which nitrosamines are 14 formed, specifically NDMA and NDEA? 15 A. I may have looked at 16 whatever documents were provided and -- 17 but I did not use any information as to 18 how nitrosamines form, to form the basis 19 for my opinion that's in my written 20 report. It's not something that I was 21 concerned with. 22 Q. Did you -- in preparing your 23 report, did you look to see how NDEA 24 specifically was formed in Mylan's</p>
<p style="text-align: right;">Page 79</p> <p>1 article's title was cut off. 2 It reads, USP Announces 3 Approval of Chapter on Nitrosamines 4 Impurities, dated December 3rd, 2021. 5 Do you see that? 6 A. Yes, I do. 7 Q. And then do -- you'll see in 8 the third paragraph, there's a quote 9 attributed to Edwin Gump, Ph.D., vice 10 president of the Small Molecules 11 Department at USP? 12 A. Yes. 13 Q. And he says that, One of the 14 things that makes nitrosamines really 15 tricky is that they actually can be 16 formed very simply through really simple 17 chemistries. 18 Do you see that? 19 A. Yes. 20 Q. You don't have any reason 21 to -- you know, putting on your organic 22 chemistry hat, do you disagree with that 23 statement in any way? 24 MR. REEFER: Object to form.</p>	<p style="text-align: right;">Page 81</p> <p>1 valsartan API? 2 A. I did not specifically look 3 to see how NDEA was formed in Mylan's 4 product. 5 Q. Do you have -- do you have 6 an idea of how NDEA was formed in Mylan's 7 product? 8 MR. REEFER: Objection. 9 Beyond the scope. Calls for 10 speculation. 11 THE WITNESS: I'm not a 12 process chemist, so I am not 13 equipped to make a determination 14 on how NDEA was formed. 15 And it just did not have any 16 influence or input into the basis 17 of my report. So it's beyond what 18 I was asked to opine on. 19 BY MR. DAVIS: 20 Q. I think I know the answer to 21 this question. 22 But you're not asserting any 23 kind of opinion, one way or the other, 24 regarding the genotoxic -- genotoxicity</p>

<p style="text-align: right;">Page 82</p> <p>1 of NDMA or NDEA, are you?</p> <p>2 A. I may be a lot of things,</p> <p>3 but I'm not a toxicologist. And the --</p> <p>4 whether or not it's a potential genotoxic</p> <p>5 impurity or not is beyond my expertise.</p> <p>6 Q. Are you familiar with -- and</p> <p>7 I think you have already mentioned it</p> <p>8 just in passing today, but you're</p> <p>9 familiar with ICH guidelines, correct?</p> <p>10 A. I'm very familiar, well,</p> <p>11 with at least some of the ICH quality</p> <p>12 guidelines.</p> <p>13 Q. Those would be the ones that</p> <p>14 are ICHQ? That start with ICHQ?</p> <p>15 A. That's correct.</p> <p>16 Q. Are you familiar with</p> <p>17 ICH M7?</p> <p>18 A. I know what M7 is. I would</p> <p>19 not say that I'm really familiar with it.</p> <p>20 Q. Did you look at it in</p> <p>21 preparing your expert report in this</p> <p>22 case?</p> <p>23 A. I did not.</p> <p>24 MR. DAVIS: Let me mark that</p>	<p style="text-align: right;">Page 84</p> <p>1 Q. If you'd flip to Page 5,</p> <p>2 Dr. Sheinin, there's a header titled,</p> <p>3 General Principles.</p> <p>4 A. Okay.</p> <p>5 Q. Take a few moments, if you</p> <p>6 would, to read that section, that's</p> <p>7 Subsection 3, General Principles, and</p> <p>8 it's on Page 5 and then goes down to</p> <p>9 the -- about the middle of Page 6.</p> <p>10 And let me know when you're</p> <p>11 ready to discuss.</p> <p>12 A. Okay.</p> <p>13 Okay. I finished reading</p> <p>14 it.</p> <p>15 Q. Let me start with a -- do</p> <p>16 you see that this guidance refers</p> <p>17 specifically to nitrosamines?</p> <p>18 MR. REEFER: Object to form.</p> <p>19 Beyond the scope. Lack of</p> <p>20 foundation.</p> <p>21 THE WITNESS: I see that it</p> <p>22 mentions N-nitroso compounds,</p> <p>23 among others.</p> <p>24 BY MR. DAVIS:</p>
<p style="text-align: right;">Page 83</p> <p>1 as Tab 7 -- sorry, that's Tab 7,</p> <p>2 Jason. I'm going to mark that as</p> <p>3 Exhibit-5.</p> <p>4 - - -</p> <p>5 (Whereupon, Exhibit</p> <p>6 Sheinin-5, No Bates, M7(R1)</p> <p>7 Assessment and Control of DNA</p> <p>8 Reactive (Mutagenic) Impurities in</p> <p>9 Pharmaceuticals to Limit Potential</p> <p>10 Carcinogenic Risk, Guidance for</p> <p>11 Industry, was marked for</p> <p>12 identification.)</p> <p>13 - - -</p> <p>14 BY MR. DAVIS:</p> <p>15 Q. Do you have that in front of</p> <p>16 you, Dr. Sheinin?</p> <p>17 A. Yes, I do.</p> <p>18 Q. Okay. The title of -- the</p> <p>19 specific title of the guidance is,</p> <p>20 Assessment and Control of DNA Reactive</p> <p>21 (Mutagenic) Impurities in Pharmaceuticals</p> <p>22 to Limit Potential Carcinogenic Risk.</p> <p>23 Do you see that?</p> <p>24 A. I see it.</p>	<p style="text-align: right;">Page 85</p> <p>1 Q. And it refers to that group</p> <p>2 that includes N-nitroso compounds as the</p> <p>3 cohort of concern of high-potency</p> <p>4 mutagenic carcinogens.</p> <p>5 Do you see that?</p> <p>6 MR. REEFER: Object to form.</p> <p>7 Beyond the scope. Lack of</p> <p>8 foundation.</p> <p>9 THE WITNESS: I see it, but</p> <p>10 it's not -- I'm not a</p> <p>11 toxicologist, so I can't evaluate</p> <p>12 how much the concern is. It's --</p> <p>13 I can see the words on the paper,</p> <p>14 but I'm not in a position to be</p> <p>15 able to judge whether they're a</p> <p>16 risk or not.</p> <p>17 BY MR. DAVIS:</p> <p>18 Q. And I'm not asking you to,</p> <p>19 Dr. Sheinin.</p> <p>20 The only purpose of this is</p> <p>21 I just want to ask you to confirm that,</p> <p>22 on its face, nitrosamines, N-nitroso</p> <p>23 compounds are subject to this guidance?</p> <p>24 MR. REEFER: Object to form.</p>

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<p>1 Beyond the scope. Lack of 2 foundation. 3 THE WITNESS: I'm not a 4 toxicologist, but I can see the 5 words on this paper -- on this 6 page. It says, N-nitroso 7 compounds. 8 BY MR. DAVIS: 9 Q. Right. And on its face, 10 that means that N-nitroso compounds are 11 subject to what's set forth in this ICH 12 M7 guidance, correct? 13 MR. REEFER: Objection. 14 Same objections. 15 THE WITNESS: I can see on 16 this page that, yes, it says 17 N-nitroso compounds. So N-nitroso 18 compounds are included in this 19 guidance. 20 But that's all I can say. 21 I'm not in a position to be able 22 to evaluate anything involved with 23 N-nitroso compounds. 24 BY MR. DAVIS:</p>	<p>1 Mylan did or did not do what you think 2 that they should have done in terms of 3 N-nitroso compounds. It's not anything 4 that I used in my report, and it's beyond 5 my expertise. 6 Q. Okay. You can put that 7 away. We'll move on. 8 You mentioned at the FDA 9 that you acquired a mass spec instrument 10 in the early 1970s, right? 11 A. Yes. 12 Q. And then -- and then you 13 coupled that with a gas chromatography 14 system? 15 A. The instrument 16 manufacturers, Varian, is the one who 17 coupled it. It's nothing that I would be 18 capable of doing. 19 But, yes, the company did 20 couple the GC with the mass spectrometer. 21 Q. So were you telling me, 22 then, that the FDA acquired a GC-MS that 23 was coupled in the early '70s as well? 24 A. No. They -- we had gas</p>
Page 87	Page 89
<p>1 Q. Right. But you would agree 2 that this guidance does require 3 manufacturers to do that evaluation, 4 correct? 5 MR. REEFER: Object to form. 6 Beyond the scope. Foundation. 7 Go ahead, if you know. 8 THE WITNESS: Again, I'm not 9 a toxicologist, so what would need 10 to be done in terms of N-nitroso 11 compounds is beyond my expertise. 12 And it does not form the basis for 13 anything that's in my report. 14 BY MR. DAVIS: 15 Q. The title of the guidance 16 is, Assessment and Control of DNA 17 Reactive Impurities. 18 Do you have any opinion, one 19 way or the other, as to whether Mylan 20 appropriately assessed or controlled for 21 potential nitrosamine impurities in its 22 valsartan? 23 A. I'm not a toxicologist, so I 24 really can't offer an opinion on whether</p>	<p>1 chromatographs already. We bought the 2 mass spectrometer. And I don't recall if 3 it was a package to get the gas 4 chromatograph, but I'm thinking we got 5 the mass spectrometer first and then 6 Varian came out with a mechanism to 7 couple a gas chromatograph to a mass 8 spectrometer. 9 And the mass spectrometer 10 that we had operated in -- you had to 11 have a vacuum, and trying to take the 12 effluent from a gas chromatograph and 13 putting it into a mass spectrometer was 14 not something that we would have been 15 able to do. And it was something that 16 eventually the instrument manufacturers 17 were able to do. 18 I don't believe that when we 19 got our mass spectrometer initially that 20 we had the capability to couple it to a 21 gas chromatograph. 22 Q. But that was done a little 23 bit later in the 1970s, it sounds like? 24 A. Yeah. Yeah.</p>

<p>Page 90</p> <p>1 Q. Is the sensitivity -- was</p> <p>2 the sensitivity of the mass spectrometer</p> <p>3 back then substantially different from</p> <p>4 what it is today?</p> <p>5 A. I don't know, but I would</p> <p>6 expect that advances have been made in</p> <p>7 mass spectrometry as well as in other</p> <p>8 types of detectors for gas</p> <p>9 chromatography.</p> <p>10 It's just the nature of the</p> <p>11 advancement in science that sensitivity</p> <p>12 is always being improved.</p> <p>13 Q. Well, at least one area</p> <p>14 that's developed is -- are you familiar</p> <p>15 with, like, predictive modeling, where</p> <p>16 you can run a chemical structure through</p> <p>17 a database and it will flag -- flag it as</p> <p>18 potentially mutagenic or genotoxic?</p> <p>19 MR. REEFER: Object to form.</p> <p>20 Beyond the scope. Lack of</p> <p>21 foundation.</p> <p>22 THE WITNESS: I'm not</p> <p>23 familiar with that type of</p> <p>24 database.</p> <p>Page 91</p> <p>1 BY MR. DAVIS:</p> <p>2 Q. Okay. Have you ever heard</p> <p>3 of Derek Nexus?</p> <p>4 A. I've heard of it. I'm not</p> <p>5 familiar with it.</p> <p>6 Q. What about QSAR generally?</p> <p>7 A. What about what?</p> <p>8 Q. Quantitative</p> <p>9 structural-activity relationships, QSAR.</p> <p>10 A. Oh. I've heard of it. I</p> <p>11 really don't know anything about it.</p> <p>12 Again, I'm not a</p> <p>13 toxicologist, so I -- I've heard of it.</p> <p>14 I don't know how it works, and I don't</p> <p>15 know how to use it.</p> <p>16 Q. You would agree, wouldn't</p> <p>17 you, that the GC and mass machines that</p> <p>18 have existed since they were coupled in</p> <p>19 the '70s, or even before then, that those</p> <p>20 were capable of detecting nitrosamines,</p> <p>21 correct?</p> <p>22 MR. REEFER: Object to form.</p> <p>23 Beyond the scope. Incomplete</p> <p>24 hypothetical.</p>	<p>Page 92</p> <p>1 THE WITNESS: I would have</p> <p>2 to know how much of any given</p> <p>3 ingredient or chemical we're</p> <p>4 talking about, in terms of whether</p> <p>5 it could be detected or not.</p> <p>6 It would -- a lot would</p> <p>7 depend on what's in the column</p> <p>8 that's in your gas chromatograph,</p> <p>9 is it going to come off? It's</p> <p>10 very hypothetical, and I really</p> <p>11 can't give you an opinion one way</p> <p>12 or the other.</p> <p>13 BY MR. DAVIS:</p> <p>14 Q. That's not something you</p> <p>15 evaluated in this case, whether GC-MS</p> <p>16 machines were capable of identifying</p> <p>17 NDEA, NDMA in Mylan's valsartan in the</p> <p>18 quantities they were present therein?</p> <p>19 MR. REEFER: Same objection.</p> <p>20 THE WITNESS: That's</p> <p>21 correct, it's nothing that I used</p> <p>22 to form my opinions in my report.</p> <p>23 MR. DAVIS: I'm going to</p> <p>24 mark Tab 11, Jason, as Exhibit-6.</p> <p>Page 93</p> <p>1 - - -</p> <p>2 (Whereupon, Exhibit</p> <p>3 Sheinin-6, No Bates, Valsartan</p> <p>4 Guidance, was marked for</p> <p>5 identification.)</p> <p>6 - - -</p> <p>7 MR. REEFER: He has it,</p> <p>8 John. He's just reviewing it.</p> <p>9 MR. DAVIS: Okay. Sure.</p> <p>10 BY MR. DAVIS:</p> <p>11 Q. Do you recognize this,</p> <p>12 Dr. Sheinin, as the 2020 version of the</p> <p>13 USP standard for valsartan?</p> <p>14 A. I see that it's the</p> <p>15 monograph, official as of May 1st of</p> <p>16 2020, USP, yes.</p> <p>17 Q. Is this the USP that's</p> <p>18 currently effective?</p> <p>19 A. I don't know if this is the</p> <p>20 one that's currently effective. I'd have</p> <p>21 to go online to the current -- to the USP</p> <p>22 online to see if there was a new version</p> <p>23 since May 1st of 2020. I can't say yes</p> <p>24 or no.</p>
--	--

<p style="text-align: right;">Page 94</p> <p>1 Q. Do you see at the top there, 2 there's an official status that says, 3 Currently official on 28 January 2022? 4 A. Yes. 5 Q. Okay. Does that suggest to 6 you that, at least as of that date, that 7 that was the current USP monograph for 8 valsartan? 9 A. Yes. 10 Q. Is there any place in this 11 2020 monograph that mentions anything 12 about nitrosamines at all? 13 A. No. 14 Q. It's not your opinion, is 15 it, then, Dr. Sheinin, that nitrosamines 16 for this monograph only need to be 17 controlled at not more than .1 percent, 18 is it? 19 MR. REEFER: Objection to 20 form. I think it's a double 21 negative. 22 But go on, if you 23 understood. 24 THE WITNESS: Can you repeat</p>	<p style="text-align: right;">Page 96</p> <p>1 toxicologist and I don't know at what 2 level those nitrosamines would have to be 3 controlled. 4 Q. They would be -- in other 5 words, what you're telling -- let me 6 crystallize what you're telling me. 7 I think what you're telling 8 me is that, aside from this USP 9 monograph, there would be other -- other 10 regulatory items, so to speak, that would 11 set different limits for nitrosamines, 12 correct? 13 A. There's always requirements 14 in an NDA or an ANDA application, in the 15 specification, that has tests that are 16 not included in the USP monograph. So 17 it's entirely possible that there could 18 be additional information in what's filed 19 at FDA than what's in a USP monograph. 20 Q. Right. And, I guess, just 21 to tag a general point on that, the USP 22 monograph is not the end-all, be-all in 23 terms of tests that are required to be 24 done on a -- in this case, an API for</p>
<p style="text-align: right;">Page 95</p> <p>1 your question? 2 BY MR. DAVIS: 3 Q. Okay. It's not your 4 opinion, is it, Dr. Sheinin, that 5 nitrosamines only need to be controlled 6 at point -- not more than .1 percent, is 7 it? 8 MR. REEFER: Object to form. 9 Do you mean per the monograph or 10 in general? 11 MR. DAVIS: I'm asking -- 12 I'm asking him generally. 13 BY MR. DAVIS: 14 Q. My question is, you've told 15 me that nitrosamines aren't mentioned 16 anywhere in this monograph. 17 My question is, does that 18 mean, in your opinion, Dr. Sheinin, that 19 nitrosamines only need to be controlled 20 at not more than .1 percent, as stated in 21 this impurity section on the USP 22 monograph? 23 A. It's not something that I 24 feel I can address, because I'm not a</p>	<p style="text-align: right;">Page 97</p> <p>1 valsartan, or another substance, correct? 2 MR. REEFER: Object to form. 3 Go ahead. 4 THE WITNESS: According to 5 the Food, Drug and -- Federal 6 Food, Drug and Cosmetic Act, a 7 drug product or a drug substance 8 or an API, if you will, if there 9 is a USP monograph, that material 10 has to meet the requirements in a 11 USP -- in the USP monograph. 12 FDA has the authority to ask 13 for additional requirements in the 14 specification that's approved 15 generally. Companies include 16 tests and procedures in their drug 17 application that are not included 18 in the USP monograph. 19 BY MR. DAVIS: 20 Q. Right. There are additional 21 tests and limits that can apply that just 22 simply aren't in the USP monograph, 23 correct? 24 A. Yes, there are -- there are</p>

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1 tests and procedures and acceptance
2 criteria in the specification that's
3 included in an approved application that
4 are not in the USP.

5 Q. And in the case of N-nitroso
6 compounds specifically, we just saw ICH
7 M7, which provides some guidance on
8 testing and limits to control for
9 nitrosamine impurities specifically per
10 that guidance, right?

11 MR. REEFER: Object to form.
12 Beyond the scope. Lack of
13 foundation.

14 THE WITNESS: I saw what was
15 on -- whatever -- the Page 5 of
16 that guidance, that it mentioned
17 N-nitroso compounds.

18 BY MR. DAVIS:
19 Q. You list a number of Mylan
20 fact witness depositions in your Exhibit
21 B to your report.

22 Do you recall listing those?

23 A. I recall that they are on
24 the list and they are things that counsel

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1 provided to me.

2 Q. Did you ask counsel if that
3 was all of the Mylan fact witness
4 depositions that have been taken in the
5 case?

6 A. I did not.

7 Q. You don't list the
8 deposition of Wayne Talton.

9 Is there -- did you know
10 that he was deposed in this case?

11 A. The name is not familiar to
12 me.

13 Q. You wouldn't know him as
14 Mylan's regulatory affairs corporate
15 witness in this case?

16 A. No, I would not.

17 [REDACTED]

18 [REDACTED]

19 [REDACTED]

20 [REDACTED]

21 [REDACTED]

22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

Page 100

1 [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 [REDACTED]

20 [REDACTED]

21 [REDACTED]

22 MR. DAVIS: Let me mark Tab
23 12, Jason. That will be
24 Exhibit-7.

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1 - - -

2 (Whereupon, Exhibit
3 Sheinin-7, MYLAN-MDL2875-00705126,
4 3/14/19 Cover Letter for Master
5 File GDUFA Complete Response
6 Letter, was marked for
7 identification.)

8 - - -

9 MR. REEFER: This is being
10 marked as 7, right, John?

11 MR. DAVIS: That's correct,
12 Exhibit-7.

13 MR. REEFER: Okay. I'm just
14 making sure I was keeping count.

15 BY MR. DAVIS:
16 Q. Dr. Sheinin, you'll see
17 there's a yellow exhibit sticker -- or
18 maybe it's not yellow if it printed in
19 black-and-white, but there's a sticker on
20 the first page that says Exhibit
21 Plaintiff Talton-11.

22 Do you see that on the top
23 right corner of the very first page of
24 the document?

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1 A. Yeah.
2 PL-Talton-11?
3 Q. Right.
4 A. Yes, I see it.
5 Q. And you'll see that the --
6 yes.
7 And you'll see that the file
8 name on that page of the file, as it was
9 produced to us by Mylan, says, DMF
10 Quality Information Amendment 20190314?
11 A. Yes.
12 Q. Okay. If you go to the
13 fourth page of the document, you'll see a
14 header, valsartan DMF Number 018253. And
15 then, Response to valsartan DMF letter,
16 dated February 5th, 2019.
17 Do you see that?
18 A. Yes.
19 [REDACTED]

Page 103

1 [REDACTED]

Page 104

1 [REDACTED]

Page 105

1 [REDACTED]

Page 106

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 BY MR. DAVIS:
24 Q. Right. And that's because

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1 counsel didn't provide you Mr. Talton's
2 testimony and this exhibit, correct?
3 MR. REEFER: Object to form.
4 Argumentative. Beyond the scope.
5 Foundation.
6 THE WITNESS: I have not
7 seen this document before. So,
8 yes, I did not receive it. I've
9 not seen it.
10 BY MR. DAVIS:
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

Page 108

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 BY MR. DAVIS:
8 Q. Turning to your report for a
9 second, Dr. Sheinin, in Paragraphs 64 to
10 66 -- and I'm going to paraphrase you
11 here, and feel free to take issue with my
12 paraphrasing if you'd like, but --
13 A. Which paragraphs again?
14 Q. Sure. Paragraphs 64 through
15 68, under the header, Mylan's Valsartan
16 API Manufactured Between Market Entry in
17 2012 and the Recalls in 2018 Complied
18 With the Standards and Specifications in
19 Place at the Time of Manufacture.
20 A. Yes.
21 Q. You write there in that
22 section -- or one of the things you write
23 is that the valsartan USP monograph did
24 not contain any testing or acceptance

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1 criteria for nitrosamine content.
2 And I'm specifically guiding
3 you to Paragraph 66.
4 Do you see that?
5 A. Yes.
6 Q. Why is that relevant to you?
7 What's the point of having that in your
8 report?
9 A. The relevance is that I'm
10 opining on the fact that Mylan's
11 valsartan API, manufactured between
12 market entry in 2012 and the recalls in
13 2018, complied with the standards and
14 specifications in place at the time of
15 the manufacture.
16 So it's relevant in that
17 there was no mention in the USP monograph
18 of the need to test for nitrosamines.
19 Q. Okay. But that doesn't mean
20 that Mylan's valsartan was okay simply
21 because it met the USP monograph,
22 correct?
23 MR. REEFER: Object to form.
24 Vague.

<p style="text-align: right;">Page 110</p> <p>1 THE WITNESS: It meant that 2 the -- Mylan's valsartan met the 3 USP monograph prior to recalls of 4 2018, and Mylan's valsartan 5 products are on the market today. 6 They meet the USP monograph. They 7 meet the specifications in the 8 FDA-approved applications. They 9 have USP on the label of the -- 10 both the drug product, valsartan 11 tablets USP, and they also include 12 the USP on the drug substance, 13 valsartan USP. 14 So at this point I've lost 15 track of what your initial 16 question was. 17 BY MR. DAVIS: 18 Q. Well, sure, let me -- let me 19 ask it this way. 20 Is it your testimony, 21 Dr. Sheinin, that between Mylan's entry 22 on the market in 2012 and the time of 23 recall in late 2018/early 2019, that 24 nitrosamines only had to be controlled at</p>	<p style="text-align: right;">Page 112</p> <p>1 monograph and they have to meet the 2 specification requirements in the 3 approved application. 4 Q. And the approved application 5 here is the ANDA, correct? 6 A. Correct. 7 Q. And that references the DMF 8 in this case by Mylan, which you said you 9 didn't review, correct? 10 A. Correct. Because drug 11 master files are not approved or not -- 12 and not not approved. 13 Q. Well, in this case, Mylan -- 14 Mylan's ANDA referenced the drug master 15 file, so it became incorporated into the 16 ANDA. 17 Do you understand that? 18 A. That's correct. And 19 that's -- that's the way it works. 20 But DMFs by themselves are 21 not approved or not -- and not not 22 approved. The FDA takes no -- no 23 regulatory action on drug master files. 24 Q. Right. But they would have</p>
<p style="text-align: right;">Page 111</p> <p>1 not more than .1 percent per the USP 2 monograph? 3 A. The monograph, as well as 4 the specification in the approved 5 application, includes, in the impurities 6 section, a requirement for any unknown 7 impurity not more than 0.1 percent. 8 So in order to meet the 9 requirements of the USP monograph and the 10 ANDA specification for the API, any other 11 unknown impurity would need to be 12 controlled to not more than 0.1 percent. 13 Q. So it is your opinion, then, 14 that during that timeframe Mylan only had 15 to control nitrosamine impurities at not 16 more than .1 percent? 17 Are you saying that the USP 18 standard governs solely Mylan's 19 marketability of its products? 20 A. I'm not equipped to discuss 21 the marketability of a product. I'm a 22 chemist, that's not my area. 23 But in order for Mylan to be 24 on the market, they have to meet the USP</p>	<p style="text-align: right;">Page 113</p> <p>1 taken an action on the ANDA in this case, 2 which incorporated, by reference, the 3 drug master file, correct? 4 A. Yeah. As I believe is 5 included in my -- in my expert report, 6 that when there's deficiencies in a drug 7 master file, the NDA or ANDA holder -- or 8 it's possible to have a DMF that 9 references another DMF. 10 So however it works, the FDA 11 would say in a letter to the applicant 12 that there's issues or deficiencies in 13 the drug master file, and the FDA would 14 send a detailed letter to the drug master 15 file holder detailing what those 16 deficiencies or issues are. But they 17 would not communicate to the NDA or ANDA 18 applicant what those deficiencies are. 19 And I think that's included 20 in my report. So that's how that works. 21 Q. Well, sure. But what I was 22 asking was whether the -- in the setup 23 that Mylan had, where they chose to 24 submit an ANDA and then incorporate, by</p>

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1 reference, their drug master file, that's
2 submitted with the ANDA to the FDA,
3 correct, and reviewed by the FDA as part
4 of the ANDA review process, is it not?
5 A. I don't think that's exactly
6 right.
7 The drug master file is
8 submitted separately to the agency, and
9 there's a letter authorizing reference to
10 the drug master file that's included in
11 the ANDA. But the ANDA and the drug
12 master file are not submitted at the same
13 time to the same place.
14 Q. Okay. Well, taking that,
15 that they can come in waves -- I take
16 your point there.
17 The point -- the point I'm
18 trying to make, though, is that when the
19 ANDA is submitted -- let's say the drug
20 master file is submitted a month
21 beforehand. When the ANDA is submitted,
22 that makes reference and incorporates by
23 reference the drug master file, that
24 becomes, essentially, part of the ANDA

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1 submission that the FDA reviews in
2 determining whether to approve the ANDA,
3 correct?
4 A. I wouldn't say -- well, from
5 a -- I'm not a lawyer, so I can't say how
6 that's incorporated -- a drug master file
7 is incorporated into the application.
8 But the drug master file may
9 or may not be reviewed for a given ANDA.
10 It depends on whether the drug master
11 file has been reviewed in the past and
12 found to be acceptable. So when a new
13 ANDA comes in, that drug master file may
14 or may not be reviewed. It depends --
15 Q. Well, let's -- well, let's
16 take Mylan's first ANDA here that was
17 approved. There were three ANDAs.
18 You're familiar with that,
19 right?
20 A. Yes.
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

Page 116

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 Q. Okay. And you just told me
14 you haven't reviewed the ANDAs in any
15 particular detail and you haven't
16 reviewed the DMF at all, correct?
17 A. Correct.
18 Q. Let's say, Dr. Sheinin, that
19 there was a discrepancy between the
20 impurity limits in the USP monograph and
21 the limits approved or set by the FDA,
22 whether approving an ANDA or in some
23 other guidance document or official FDA
24 document that sets limits, which would

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1 control in that instance? Would the USP
2 monograph limit control or would the FDA
3 approved limit control?
4 A. If I remember correctly, the
5 USP acceptance criteria would control.
6 But I'm not 100 percent certain of that.
7 MR. DAVIS: I'm going to
8 mark Tab 10, Jason, as Exhibit-8.
9 - - -
10 (Whereupon, Exhibit
11 Sheinin-8, No Bates, Impurities in
12 Drug Products and Drug
13 Substances - A USP Approach, was
14 marked for identification.)
15 - - -
16 BY MR. DAVIS:
17 Q. Do you have this set of USP
18 slides in front of you, Dr. Sheinin?
19 A. I do.
20 Q. Do you see that it's titled,
21 Impurities in Drug Products and Drug
22 Substances - A USP Approach?
23 A. Yes.
24 Q. Do you know who

<p style="text-align: right;">Page 118</p> <p>1 Dr. Ravichandran is?</p> <p>2 A. I do. I hired him.</p> <p>3 Q. Have you seen this</p> <p>4 presentation before?</p> <p>5 A. I don't believe I have.</p> <p>6 Do you know where it was</p> <p>7 given?</p> <p>8 Q. You might see in very, very</p> <p>9 grayed-out text on the first page that</p> <p>10 says, Last update, March 2018.</p> <p>11 Do you see that?</p> <p>12 A. On the first page here of</p> <p>13 the exhibit? I don't see anything about</p> <p>14 that.</p> <p>15 Q. Okay. It might be too</p> <p>16 grayed out in the way it printed.</p> <p>17 I'll represent to you that</p> <p>18 the document --</p> <p>19 A. Oh, yeah. It's very, very</p> <p>20 light. I can't -- I can't see that.</p> <p>21 Q. And then even smaller text</p> <p>22 on the bottom right corner of each page,</p> <p>23 also grayed out, is a, Copyright 2020,</p> <p>24 USP.</p>	<p style="text-align: right;">Page 120</p> <p>1 THE WITNESS: I think he's</p> <p>2 knowledgeable to the point that</p> <p>3 his supervisor approved giving</p> <p>4 this presentation.</p> <p>5 Again, I can't say that he's</p> <p>6 more or less knowledgeable about</p> <p>7 the topic than other scientists at</p> <p>8 USP. It's -- I -- there's only a</p> <p>9 handful of USP scientists who are</p> <p>10 still there from when I left.</p> <p>11 BY MR. DAVIS:</p> <p>12 Q. Flip to Page 9 as it's</p> <p>13 numbered on these slides.</p> <p>14 And it's, again, in very</p> <p>15 small numbering, gray text in the bottom</p> <p>16 right corner. You'll see a slide that's</p> <p>17 titled, Contents.</p> <p>18 MR. REEFER: John, if you're</p> <p>19 going to ask questions about, you</p> <p>20 know, the substance of this, can</p> <p>21 we have an opportunity to go</p> <p>22 through it? I think Dr. Sheinin</p> <p>23 said he had not seen the</p> <p>24 presentation before.</p>
<p style="text-align: right;">Page 119</p> <p>1 Do you see that?</p> <p>2 A. I see something. I can't</p> <p>3 tell you what it says.</p> <p>4 Q. Okay. Do you hold</p> <p>5 Dr. Ravichandran in high regard?</p> <p>6 MR. REEFER: Object to form.</p> <p>7 THE WITNESS: Yes.</p> <p>8 BY MR. DAVIS:</p> <p>9 Q. You think he's quite</p> <p>10 knowledgeable?</p> <p>11 MR. REEFER: Object to form.</p> <p>12 Vague.</p> <p>13 THE WITNESS: I think he's</p> <p>14 knowledgeable. I don't know that</p> <p>15 he's more or less knowledgeable</p> <p>16 than other scientists at USP.</p> <p>17 BY MR. DAVIS:</p> <p>18 Q. Do you think he's quite</p> <p>19 knowledgeable regarding the USP approach</p> <p>20 to impurities and drug products and drug</p> <p>21 substances, which is the title of this</p> <p>22 presentation?</p> <p>23 MR. REEFER: Object to form.</p> <p>24 Vague. Foundation.</p>	<p style="text-align: right;">Page 121</p> <p>1 MR. DAVIS: I mean, sure.</p> <p>2 It's 90 pages, Jason, and I only</p> <p>3 have questions regarding, at most,</p> <p>4 a couple of them. So I'm not</p> <p>5 sure --</p> <p>6 MR. REEFER: All right.</p> <p>7 MR. DAVIS: -- if fully</p> <p>8 reviewing the document in</p> <p>9 different aspects of it will</p> <p>10 pertain to what I want to talk</p> <p>11 about.</p> <p>12 I mean, what if we -- what</p> <p>13 if we did this, I'll ask my</p> <p>14 questions, and if Dr. Sheinin</p> <p>15 wants to review the pages</p> <p>16 surrounding that for context, I'm</p> <p>17 happy to let him do that.</p> <p>18 MR. REEFER: Yeah. John,</p> <p>19 I'm not trying to interrupt you.</p> <p>20 I just want to give him a fair</p> <p>21 opportunity based on his testimony</p> <p>22 he hadn't seen it before.</p> <p>23 So if the doctor says that,</p> <p>24 you know, he needs to take a</p>

<p>Page 122</p> <p>1 minute to understand it, I just 2 ask that you let him do so. 3 That's all. 4 Fair enough? 5 MR. DAVIS: Fair enough. 6 MR. REEFER: Cool. Thank 7 you. 8 BY MR. DAVIS: 9 Q. So you're at Page 9, the 10 table of contents for this presentation, 11 Dr. Sheinin? 12 A. I see on Page 3 of what 13 you've given me something that says, 14 Contents. I don't know what's -- I can't 15 see any page numbers. 16 Q. Yes. Is it -- did it print 17 out for you as four slides to a page? 18 A. Two slides to a page. 19 Q. Two slides to a page. 20 A. Yes. 21 Q. Okay. I see. 22 So the contents section 23 actually appears twice, it appears. So 24 we can -- we can stick on the one you're</p> <p>Page 123</p> <p>1 on. 2 And, I guess, do you see 3 where it says -- there's a header, 4 Guidelines, guidances? And it says, ICH 5 FDA, below that? 6 A. Yes. 7 Q. Why would -- why would 8 Dr. Ravichandran include ICH/FDA 9 guidelines and guidances in a 10 presentation that's titled, A USP 11 Approach to Impurities? 12 MR. REEFER: Object to form. 13 Foundation. Calls for 14 speculation. 15 THE WITNESS: I don't know 16 why he included them. I'd have to 17 ask him why he included this as a 18 topic. 19 BY MR. DAVIS: 20 Q. Why would they be -- 21 A. I'm not -- 22 Q. Why would they be -- 23 A. I'm not in a position -- 24 MR. REEFER: Can you let him</p>	<p>Page 124</p> <p>1 finish, John? Sorry about that. 2 MR. DAVIS: Yes, go ahead. 3 THE WITNESS: I'm not in a 4 position to be able to say why he 5 included them. I don't know. 6 BY MR. DAVIS: 7 Q. Why would -- let me ask it 8 this way, then: Why would ICH/FDA 9 guidelines and guidances be germane to 10 discussing in a presentation titled, A 11 USP Approach to Impurities? 12 MR. REEFER: Object to form. 13 Foundation. Calls for 14 speculation. 15 THE WITNESS: I can't tell 16 you exactly why. I can tell you 17 that there were times when ICH 18 created a guidance, in FDA 19 perspective, in ICH perspective, 20 when they created a guideline 21 where USP eventually modified a 22 general chapter to be in agreement 23 with what ICH did. 24 So that's the only reason I</p> <p>Page 125</p> <p>1 might be able to offer. But I 2 don't know -- I don't know what 3 was in Ravi's mind as to why he 4 included them in this 5 presentation. It's beyond my 6 capability to tell you why. 7 BY MR. DAVIS: 8 Q. Okay. Turn, if you would, 9 to the slide that's numbered 36. 10 A. What's the -- I don't see 11 any numbers on any of them, so what's the 12 heading? 13 Q. Okay. Flip until you find a 14 USP sort of face page that says, 15 Discussion, in bold lettering. It should 16 be about 15 or so pages in. 17 A. I see something that says 18 Discussion and contents listed again. 19 Q. Yes, correct. 20 And then if you flip a few 21 pages further than that, you'll see a 22 question and answer. 23 The question is, If a 24 manufacturer controls impurities and</p>
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1 degradation products in accordance with
2 only a pharmacopeial monograph, is that
3 acceptable to the regulators?
4 Do you see that?
5 A. No.
6 Q. It should be four -- the
7 fifth slide after that discussion face
8 page.
9 A. So if we're counting
10 slides --
11 MR. REEFER: John, would you
12 mind if I went over and helped a
13 little bit?
14 MR. DAVIS: Sure. If you
15 know where it is, Jason, feel free
16 to show it to him.
17 MR. REEFER: I think the
18 challenge we're facing is the way
19 it's printed, the slide number is
20 super-duper faint.
21 And so if you don't mind,
22 I'm going to stand up and just
23 walk around the table.
24 MR. DAVIS: Okay. Not a

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1 problem.
2 THE WITNESS: Maybe I had
3 the wrong discussion slide.
4 MR. REEFER: I think there's
5 a -- I think there's a number of
6 instances where the heading,
7 Discussion, appears, and I think
8 you guys might have landed on
9 different pages.
10 But, ultimately, Mr. Davis
11 will confirm. But the top of the
12 slide that I'm looking at, John,
13 says, Source of impurities, and
14 it's got a little demonstrative.
15 And then below that it's the
16 second slide that begins with
17 question.
18 MR. DAVIS: Yes, that's
19 right.
20 Thanks, Jason.
21 MR. REEFER: You're welcome.
22 BY MR. DAVIS:
23 Q. Okay. So you'll see the
24 question presented there is, If a

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1 manufacturer controls impurities and
2 degradation products in accordance with
3 only a pharmacopeial monograph, is that
4 acceptable to the regulators?
5 Do you see that?
6 A. I see it.
7 Q. And then Ravi responds to
8 that question by saying, in the second
9 bullet point of his answer, that, A
10 particular manufacturer's manufacturing
11 method for formulation components may
12 lead to unexpected impurities due to a
13 different route of synthesis, different
14 reagents, et cetera. Different processes
15 may lead to different impurities.
16 Do you see that?
17 A. Yes.
18 Q. And then -- then he
19 continues in the third bullet, it says,
20 If an individual monograph is inadequate
21 to control an impurity, the manufacturer
22 is responsible for developing and
23 validating appropriate analytical
24 procedures, establishing acceptance

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1 criteria, and communicating with USP.
2 Do you see that?
3 A. Yes.
4 Q. Okay. At any time between
5 2012 and '18, did you see any evidence
6 that Mylan had attempted to communicate
7 with USP regarding setting an acceptance
8 criteria and test for NDMA or NDEA?
9 A. I did not see anything
10 that -- of that nature.
11 MR. REEFER: Object to form
12 and scope.
13 But go ahead.
14 BY MR. DAVIS:
15 Q. Do you disagree with the way
16 that Ravi has answered the question as
17 presented?
18 MR. REEFER: Object to form
19 and scope.
20 THE WITNESS: This is --
21 this is why, when I was at USP, we
22 developed the flexible monograph
23 approach. Because if the
24 innovator either synthesizes their

<p style="text-align: right;">Page 130</p> <p>1 API themselves or purchases it 2 from a third party and an ANDA 3 comes along and a generic company 4 purchases the active ingredient 5 from a different source that's 6 using a different manufacturing 7 procedure, they almost certainly 8 will introduce a different set of 9 impurities; some may be the same 10 as in the innovator's product, 11 some may be different. 12 And USP created this 13 flexible monograph approach 14 between Roger Williams and myself 15 and another chemist who worked for 16 me. And we have a procedure where 17 a company, as it says here, if the 18 individual monograph is inadequate 19 to control the impurity, the 20 manufacturer is responsible for 21 developing, validating appropriate 22 analytical procedures and 23 communicating with USP. 24 So that's a way for the</p>	<p style="text-align: right;">Page 132</p> <p>1 Q. Do you agree that 2 manufacturers are responsible for 3 evaluating their manufacturing method for 4 these different impurities that may 5 result from that specific method that 6 they're undertaking? 7 MR. REEFER: Object to form. 8 Scope. 9 THE WITNESS: I would agree 10 that manufacturers are responsible 11 for the analytical methods that 12 are used to control impurities in 13 their drug substance and drug 14 product, if that's what you're 15 asking. 16 BY MR. DAVIS: 17 Q. Right. They're responsible 18 for evaluating their manufacturing method 19 for potentially different impurities and 20 then if they -- if they find them or 21 are -- let me strike that. 22 Manufacturers are 23 responsible for both evaluating their 24 manufacturing method for these different</p>
<p style="text-align: right;">Page 131</p> <p>1 generic to meet the USP monograph, 2 even if they have a different set 3 of impurities. 4 And the way that works, 5 then, if there would be more than 6 one impurity procedure, as I 7 mention in my report, that I 8 don't -- I'm not sure that I 9 mentioned this part in the report, 10 but if you're using Impurity 11 Procedure 1, you don't have to say 12 anything. If you're using 13 Impurity Procedure 2, you would 14 have to say something in your 15 labeling. And I give an example 16 in my report to that extent. 17 So that's -- that's the 18 premise for why we developed this 19 flexible monograph approach. 20 BY MR. DAVIS: 21 Q. So what Ravi is essentially 22 describing here in his answer is the 23 flexible monograph approach, correct? 24 A. Essentially, yes.</p>	<p style="text-align: right;">Page 133</p> <p>1 impurities, like Ravi mentions, and then 2 once identified, they are also 3 responsible for developing controls for 4 them, which is what Ravi describes in the 5 third bullet of his answer, correct? 6 MR. REEFER: Object to form. 7 Scope. 8 You can answer. 9 THE WITNESS: Companies are 10 responsible for developing the 11 analytical methods and validating 12 them to control whatever 13 impurities are found in their drug 14 substance or in their drug 15 product. 16 BY MR. DAVIS: 17 Q. Well, they're not -- would 18 you agree, manufacturers aren't just 19 responsible for controlling for 20 impurities they happen to find in their 21 drug substances or products, they're also 22 responsible for evaluating the process 23 chemistry to predict potential impurities 24 that may arise from the chemical</p>

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1 reactions that take place, right?
2 MR. REEFER: Object to form.
3 Beyond the scope.
4 THE WITNESS: That's a
5 position or a responsibility for a
6 process chemist who is designing
7 the process. That's not something
8 that I'm familiar with doing.
9 BY MR. DAVIS:
10 Q. But you're --
11 A. I can't agree or disagree
12 with you.
13 Q. Okay.
14 MR. DAVIS: Let me mark Tab
15 13, Jason.
16 MR. REEFER: Can we put the
17 slides away, John, the USP stuff?
18 MR. DAVIS: Yes, for now.
19 MR. REEFER: Okay. That was
20 ominous.
21 THE WITNESS: Can we go off
22 the record for a second?
23 MR. DAVIS: Sure. Yes.
24 MR. REEFER: I'm sorry,

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1 before we do, John, can you just
2 say again what you want me to get?
3 MR. DAVIS: Yes. Tab 13.
4 MR. REEFER: Tab 13?
5 MR. DAVIS: Yes. I'm
6 marking it as Exhibit-9, before we
7 go off the record.
8 - - -
9 (Whereupon, Exhibit
10 Sheinin-9, No Bates, FAQs: Organic
11 Impurities, was marked for
12 identification.)
13 - - -
14 MR. DAVIS: Okay. We can go
15 off.
16 VIDEO TECHNICIAN: Going off
17 the record. The time is
18 12:37 p.m.
19 - - -
20 (Whereupon, a discussion off
21 the record occurred.)
22 - - -
23 VIDEO TECHNICIAN: We are
24 back on the record. The time is

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1 12:38 p.m.
2 BY MR. DAVIS:
3 Q. Okay. Do you have what's
4 been marked as Exhibit-9 in front of you,
5 Dr. Sheinin?
6 A. Yes, Tab 13. I'm trying to
7 write down the numbers. That's 9.
8 Okay. Yes, I have it.
9 Q. You'll see that it's an FAQ
10 document, FAQs: Organic impurities.
11 Do you see that?
12 A. I see that. I see also it's
13 a -- something from USP.
14 Q. Correct. It's been pulled
15 from the USP website. The URL is at the
16 bottom, <https://www.usp.org>, frequently
17 asked questions, organic impurities.
18 Do you see that?
19 A. Yes.
20 Q. And one of the FAQs at the
21 bottom, specifically the fourth one at
22 the bottom of Page 1, is, What does it
23 mean to characterize the impurity profile
24 of a product?

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1 Do you see that?
2 A. Yes.
3 Q. And then there's an answer
4 that appears on Page 2 of 3, correct?
5 A. Where is the answer?
6 Q. The answer appears on the
7 next page. It starts with, As described
8 in applicable guidance.
9 Do you see that?
10 A. Oh, so this is -- this is
11 answering all four of these questions in
12 one --
13 Q. No, no. What I've done --
14 I'll explain --
15 MR. REEFER: It looks like
16 it's probably a drop-down,
17 Dr. Sheinin, so.
18 MR. DAVIS: That's correct.
19 MR. REEFER: If you just
20 click on --
21 MR. DAVIS: He's right.
22 BY MR. DAVIS:
23 Q. It's a drop-down. And to
24 make the document less lengthy, I've only

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1 dropped down the question that I'm
2 interested in seeing the answer to.
3 A. Oh, okay.
4 MR. REEFER: Then I'll
5 object on the basis that we don't
6 have the complete document before
7 us.
8 But with that said, if you
9 want to ask questions about it, go
10 ahead.
11 MR. DAVIS: Sure.
12 BY MR. DAVIS:
13 Q. So do you see where the
14 answer to that question, What does it
15 mean to characterize the impurity profile
16 of a product, starts on Page -- the next
17 page?
18 A. I'd like to read it. I'd
19 like to --
20 Q. Sure. Take a moment to read
21 it.
22 A. -- be able to read it.
23 Okay.
24 Q. Okay. Have you had a chance

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1 to read the answer that USP provides to
2 that question?
3 A. Yes.
4 Q. And it starts with -- it
5 starts with, As described in the --
6 sorry. What was that, Dr. Sheinin?
7 A. I was going to say, are
8 these next bullets, are they part of the
9 answer? Or are they --
10 Q. No, those are additional
11 frequently asked questions regarding
12 organic impurities that come up.
13 So what I'm directing your
14 attention to --
15 A. Okay.
16 Q. -- is the question and
17 answer that I read out for you, which is,
18 What does it mean to characterize the
19 impurity profile of a product? And then
20 the answer that USP provides.
21 Do you understand that?
22 A. Yes.
23 Q. Okay. And the first part of
24 the answer starts with, As described in

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1 applicable guidance, which include but
2 are not limited to -- and then it refers
3 to some of the ICHQ guidances.
4 Do you see that?
5 A. Yes.
6 MR. REEFER: Objecting to
7 the form. Beyond the scope. But,
8 go ahead. Sorry.
9 BY MR. DAVIS:
10 Q. So would you agree that even
11 if there is a USP monograph for a
12 product, that doesn't mean that the
13 manufacturer doesn't also have to comply
14 with other applicable guidance, for
15 example, such as ICH guidances as the USP
16 states here, correct, especially
17 regarding organic impurities, right?
18 MR. REEFER: Object to form.
19 Beyond the scope.
20 Go ahead, Dr. Sheinin.
21 THE WITNESS: I believe USP
22 is in agreement with the ICH
23 guidances, in terms of how
24 impurities are handled in their

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1 monographs. So there's -- they
2 are in agreement.
3 BY MR. DAVIS:
4 Q. Well, my question, and maybe
5 you're answering it in an indirect way,
6 but my question is, even if there is a
7 USP monograph for a product, that doesn't
8 mean that any other applicable guidances,
9 as USP terms it here, including,
10 specifically, ICH guidances, that those
11 aren't -- that those aren't likewise
12 applicable even in the presence of a USP
13 monograph?
14 MR. REEFER: Same objection.
15 Go ahead, Doctor.
16 THE WITNESS: FDA -- FDA
17 says guidances are suggestions.
18 So I -- there are other approaches
19 that a company can take that could
20 differ from an ICH guidance, as
21 well as an FDA guidance.
22 So I can't say that
23 companies are required to follow
24 other guidances. They are not

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1 required to. They can have
2 different approaches.
3 BY MR. DAVIS:
4 Q. If a company were to take a
5 different approach under an ICH guidance,
6 isn't that something they would have to
7 consult with the FDA about first?
8 MR. REEFER: Objection.
9 Beyond the scope.
10 THE WITNESS: FDA's
11 guidances -- ICH guidances, in and
12 of themselves, don't have anything
13 to do with FDA, sort of. FDA has
14 to publish those guidances before
15 they become FDA official
16 guidances.
17 But once they -- once they
18 publish them, there's no
19 difference between an ICH guidance
20 and an FDA guidance. They're one
21 and the same. So I can't
22 distinguish an FDA guidance from
23 an ICH guidance.
24 BY MR. DAVIS:

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1 Q. My general question, though,
2 is, even where a USP monograph exists,
3 there are other applicable guidances,
4 regulations, et cetera, that don't just
5 go away, right?
6 MR. REEFER: Object to form.
7 Beyond the scope.
8 THE WITNESS: I don't -- I
9 don't discuss these other ICH
10 guidances or other FDA guidances
11 to form the basis of my opinion in
12 my report. So I'm -- I'm at a
13 loss to understand what you're
14 really asking me.
15 BY MR. DAVIS:
16 Q. Well, what I'm asking you,
17 and I'll phrase it differently, but just
18 because, you know, you haven't talked
19 about it in your report doesn't mean I'm
20 not entitled to ask you a question about
21 it.
22 My -- let me ask it this
23 way: When there's a USP monograph, the
24 USP monograph doesn't just supercede

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1 other applicable FDA guidances,
2 regulations or other FDA authorities that
3 exist, right?
4 A. As a layperson, not a
5 lawyer, I can't really comment on the
6 legal aspects of that. So it's difficult
7 for me to give you an answer to that.
8 From a legal perspective, it's out of my
9 area.
10 Q. So you're not holding
11 yourself out as a regulatory expert?
12 A. I'm not holding myself out
13 as a legal expert.
14 Q. Well, my question is a
15 regulatory one, not a legal one.
16 My question is, when there
17 is a USP monograph for a product, does
18 that supercede and just make, you know,
19 irrelevant other -- other applicable
20 regulations or guidances, including, for
21 example, ICH guidances that the FDA has
22 adopted?
23 A. I think I said earlier that
24 USP in general is in conformance with ICH

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1 guidances. So I don't know that there's
2 a difference there.
3 MR. REEFER: John, if you're
4 happening to transition, do you
5 want to talk a little bit about
6 planning? We've been on about an
7 hour and 50 minutes here.
8 MR. DAVIS: Let me just
9 finish this document, and then we
10 can talk about that.
11 BY MR. DAVIS:
12 Q. If you look at the next
13 paragraph, Dr. Sheinin, it says, The
14 methods used to characterize an impurity
15 profile include, but are not limited to,
16 a sound scientific appraisal of the
17 chemical reactions involved in the
18 synthesis of the drug substance and the
19 impurities associated with raw materials,
20 et cetera, et cetera.
21 Do you see that?
22 A. Yes.
23 Q. That's consistent with what
24 Ravi is saying in his presentation we

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1 looked at in Exhibit-8, right, that you
2 can't just rely on a USP monograph, you
3 have to do a sound scientific appraisal
4 of your own manufacturing method, right?
5 MR. REEFER: Object to form.
6 Asked and answered.
7 THE WITNESS: The -- whoever
8 is developing the process to
9 create the drug substance is a
10 process chemist, and they would be
11 the ones to understand that
12 process.
13 It's not something that I
14 feel comfortable or capable of
15 second-guessing what a process
16 chemist would do. It's not
17 something that I have done, as I
18 have not worked in the industry,
19 and it's not something I've done
20 where you have to scale up a
21 process. It's just not within my
22 expertise.
23 BY MR. DAVIS:
24 Q. And I'm not -- I'm not

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1 asking you, Dr. Sheinin, to comment on
2 the substance of any particular
3 scientific appraisal of impurities that
4 was done by anyone, including Mylan.
5 I'm just asking you to
6 confirm what USP is saying here and what
7 Ravi said in his presentation we just
8 looked at in Exhibit-8, that such an
9 obligation exists?
10 MR. REEFER: Object to the
11 form. Scope.
12 THE WITNESS: And I think I
13 discussed before about the purpose
14 of an analytical method is to
15 detect and quantify, or in some
16 cases to qualify, impurities in
17 these materials.
18 So I would have to say that
19 there needs to be analytical
20 procedures to control impurities
21 in drug substances and drug
22 products.
23 BY MR. DAVIS:
24 Q. Not just analytical

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1 procedures, though; there actually has to
2 be -- and I hear you when you say this is
3 a process chemist's job to do
4 substantively, but there has -- there has
5 to be an evaluation, i.e., what -- in the
6 USP's terms, a quote, sound scientific
7 appraisal of the chemical reactions.
8 Do you disagree that that's
9 what the -- do you disagree with this USP
10 document here, that that obligation
11 exists?
12 MR. REEFER: Object to form.
13 Scope.
14 But go ahead, Doctor, you
15 can answer.
16 THE WITNESS: I'm rereading
17 this paragraph.
18 I have difficulty in putting
19 into general terms this. Yes, I
20 think you need to be able to look
21 at your analytical method and have
22 a technique, whatever your
23 detection is, to be able to
24 identify whatever impurities are

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1 in the -- whatever analyte you're
2 looking for.
3 BY MR. DAVIS:
4 Q. Okay. But that's analytical
5 chemistry.
6 What --
7 A. That -- that's what I can
8 talk to.
9 Q. Okay. So you have no
10 opinion on whether a manufacturer is
11 required to do a sound scientific
12 appraisal of the chemical reactions
13 involved in its manufacturing process?
14 A. I did not use anything in
15 this -- that's discussed in this document
16 to form the basis of my opinions about
17 USP.
18 As I mention, I did talk
19 about the flexible monograph approach,
20 and I understand that different routes of
21 synthesis can lead to different
22 impurities. And that's a way for USP to
23 be able to have companies able to meet
24 the requirements of the monograph, even

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1 when the impurity profile is different
2 than what is there in the -- from the
3 innovator product.
4 Q. And as part of that flexible
5 monograph approach, that requires
6 somebody to look at how -- how their
7 method of manufacture may differ from
8 another method and to predict the kinds
9 of impurities that may arise from that --
10 from that -- those changes in the
11 manufacturing method, correct?
12 That's part of the sound
13 scientific appraisal that the USP is
14 referring to here, is it not?
15 MR. REEFER: Object to form.
16 Scope.
17 Go ahead, Doctor, you can
18 answer.
19 THE WITNESS: I'll have to
20 fall back on what I've said.
21 There has -- the method that's
22 used is different depending on
23 what the impurity profile is.
24 So there's a -- that's why

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1 USP created the flexible monograph
2 approach.
3 BY MR. DAVIS:
4 Q. Are you familiar with FDA
5 guidances on conducting risk assessments?
6 A. On what?
7 Q. Conducting risk assessments?
8 A. For nitrosamines or just in
9 general?
10 Q. No, generally.
11 A. No, I'm not.
12 Q. Okay. And in working on
13 your report, did you see any evidence
14 that Mylan had done a sound scientific
15 appraisal of the chemical reactions
16 involved in the synthesis of Mylan's
17 valsartan API for impurities?
18 MR. REEFER: Objection to
19 form. I'm sorry, John. I thought
20 you were done. I apologize.
21 Objection to form. Beyond
22 the scope. Asked and answered.
23 THE WITNESS: I did not look
24 to see if there was anything as

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1 you described. I did not go
2 through the drug master file,
3 which is where any information
4 like that would have -- would have
5 been.
6 There was really nothing in
7 the application, in the ANDA that
8 I looked at, that contained any
9 information of that type. I did
10 not see anything. I have no way
11 of knowing if it's there or not.
12 BY MR. DAVIS:
13 Q. Let's say that someone did
14 do a sound scientific appraisal and it
15 led them to believe they might be
16 creating nitrosamine by-products in their
17 drug substance.
18 Are you with me?
19 MR. REEFER: What's that,
20 John? You broke up.
21 MR. DAVIS: Sure.
22 BY MR. DAVIS:
23 Q. I'm asking you a
24 hypothetical, Dr. Sheinin.

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1 The hypothetical is, let's
2 say there was someone at a generic
3 manufacturer who did a sound scientific
4 appraisal of the chemical reactions for
5 an API drug product substance and
6 believed, as a result of that sound
7 scientific appraisal, that the process
8 would create nitrosamine by-products.
9 Do you follow me?
10 A. I follow you.
11 Q. What would be their
12 obligation under applicable guidances and
13 regulations to do next, do you know?
14 MR. REEFER: Objection to
15 form. Incomplete hypothetical.
16 Beyond the scope. And foundation.
17 But go ahead.
18 THE WITNESS: I'm not
19 prepared to answer hypothetical
20 questions. It's --
21 BY MR. DAVIS:
22 Q. There's no basis for you not
23 to answer any question.
24 MR. REEFER: John, you

<p style="text-align: right;">Page 154</p> <p>1 interrupted him.</p> <p>2 MR. DAVIS: Well, look, he's</p> <p>3 saying he's not willing to answer</p> <p>4 a hypothetical question. That's</p> <p>5 not how this works. I'm</p> <p>6 entitled --</p> <p>7 MR. REEFER: He wasn't --</p> <p>8 MR. DAVIS: -- to ask</p> <p>9 questions --</p> <p>10 MR. REEFER: He wasn't --</p> <p>11 John, he wasn't even able to</p> <p>12 finish his answer. So I think</p> <p>13 it's a little bit presumptuous to</p> <p>14 suggest how he was going to</p> <p>15 respond in totality. Perhaps --</p> <p>16 BY MR. DAVIS:</p> <p>17 Q. You followed --</p> <p>18 MR. REEFER: -- you should</p> <p>19 let him respond.</p> <p>20 BY MR. DAVIS:</p> <p>21 Q. You followed my hypothetical</p> <p>22 question.</p> <p>23 What's your answer to it,</p> <p>24 Dr. Sheinin?</p>	<p style="text-align: right;">Page 156</p> <p>1 under the regulations, to do next, do you</p> <p>2 know?</p> <p>3 MR. REEFER: Object --</p> <p>4 objection to form. Beyond the</p> <p>5 scope. Incomplete hypothetical.</p> <p>6 And foundation.</p> <p>7 Go ahead, Doctor, if you</p> <p>8 know.</p> <p>9 THE WITNESS: I don't know</p> <p>10 what the obligation is under</p> <p>11 applicable guidance. I -- I have</p> <p>12 to go back and reread some of</p> <p>13 those guidances to see if there is</p> <p>14 language to that effect that says</p> <p>15 exactly what you said.</p> <p>16 BY MR. DAVIS:</p> <p>17 Q. Would it be your</p> <p>18 expectation -- and I get that you haven't</p> <p>19 actually reviewed the necessary documents</p> <p>20 in this case.</p> <p>21 But would it be your</p> <p>22 expectation that Mylan, here, did a sound</p> <p>23 scientific appraisal for potential</p> <p>24 genotoxic impurities, based on its</p>
<p style="text-align: right;">Page 155</p> <p>1 MR. REEFER: Object to form.</p> <p>2 Incomplete hypothetical. Beyond</p> <p>3 the scope. And foundation.</p> <p>4 But go ahead, Doctor, you</p> <p>5 can continue your answer.</p> <p>6 THE WITNESS: I would have</p> <p>7 to have some data, I would have to</p> <p>8 have some real information to be</p> <p>9 able to address a hypothetical</p> <p>10 question.</p> <p>11 It depends. It could be</p> <p>12 yes, it could be no. It's just --</p> <p>13 it's hypothetical. It's not real</p> <p>14 world.</p> <p>15 BY MR. DAVIS:</p> <p>16 Q. No. I respectfully and</p> <p>17 wholeheartedly disagree.</p> <p>18 I'm asking you, not</p> <p>19 quantitatively, I'm asking you</p> <p>20 qualitatively, if a person at a</p> <p>21 pharmaceutical manufacturer did a sound</p> <p>22 scientific appraisal and said, oh, we</p> <p>23 might be creating nitrosamine</p> <p>24 by-products, what's their obligation,</p>	<p style="text-align: right;">Page 157</p> <p>1 detailed laboratory process for creating</p> <p>2 valsartan API?</p> <p>3 MR. REEFER: Object to form.</p> <p>4 Beyond the scope.</p> <p>5 You almost acknowledge this</p> <p>6 is beyond the scope, John. I</p> <p>7 mean, you keep asking these</p> <p>8 questions. But, you know, at some</p> <p>9 point there's got to be some</p> <p>10 connection to the report, right?</p> <p>11 But with that being said, go</p> <p>12 ahead, Doctor, if you can --</p> <p>13 MR. DAVIS: Let me respond</p> <p>14 to that briefly, Jason. I'm</p> <p>15 entitled to ask him about what's</p> <p>16 in his report. I'm also entitled</p> <p>17 to point out things that he hasn't</p> <p>18 looked at, at all, or that he</p> <p>19 might -- he might think relevant</p> <p>20 or that he might, if he hasn't</p> <p>21 reviewed them, might -- you know,</p> <p>22 this is in his wheelhouse.</p> <p>23 So, you know, I'm entitled</p> <p>24 to ask the question even if it's</p>

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1 not in the report, because it's
2 part of his -- his 40 years of
3 work at the regulator and at USP,
4 and it's tangential to what he's
5 got in his report.
6 So, yeah, I'm entitled to
7 ask the question.
8 MR. REEFER: Well, that's
9 incorrect, John. You can't force
10 him to offer opinions that he
11 hasn't formulated for purposes of
12 this litigation on the spot, on
13 the fly, based on your
14 hypotheticals.
15 He says that he hasn't done
16 this analysis. He's not offering
17 the opinion on whether Mylan's DMF
18 was adequate or otherwise.
19 BY MR. DAVIS:
20 Q. Would you expect that it was
21 adequate, given what you know about the
22 facts of this case?
23 MR. REEFER: Objection to
24 form. Foundation. Scope.

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1 Go ahead.
2 BY MR. DAVIS:
3 Q. Would you expect,
4 Dr. Sheinin, that Mylan did, in fact, do
5 a sound scientific appraisal for
6 potential genotoxic impurities, based on
7 its detailed laboratory process, when, in
8 fact, there were genotoxic impurities in
9 Mylan's valsartan?
10 Would you expect --
11 MR. REEFER: Object to form.
12 BY MR. DAVIS:
13 Q. -- they did do that, given
14 what the history showed?
15 MR. REEFER: Object to form.
16 It's compound. Beyond the scope.
17 Lack of foundation. Incomplete
18 hypothetical.
19 But go ahead, Doctor.
20 THE WITNESS: The fact that
21 Mylan is on the market and FDA has
22 not, again, recalled or asked
23 Mylan to recall their product says
24 to me that their DMF is adequate

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1 and FDA has no reason to take
2 other regulatory action.
3 BY MR. DAVIS:
4 Q. Are you -- sir, are you not
5 aware that Mylan recalled every single
6 lot and batch of valsartan API that was
7 on the market in 2018 and 2019? Are you
8 not aware of that fact?
9 A. I'm aware of that. I'm also
10 aware that Mylan is back on the market.
11 Q. Okay. But you haven't --
12 we've gone over this about four or five
13 times today.
14 You have no idea the
15 circumstances how they got back on the
16 market, do you?
17 MR. REEFER: Object to form.
18 Argumentative. Beyond the scope.
19 MR. DAVIS: Well, he says
20 it's not in his report, and yet he
21 keeps bringing up the fact that
22 Mylan is back on the market, and
23 he doesn't know anything about how
24 they got back on the market.

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1 So I'm happy -- if you want
2 me to stick to your report,
3 Dr. Sheinin, you have to stick to
4 your report, too. And you brought
5 this up six times, but you haven't
6 looked at it at all.
7 MR. REEFER: Because, John,
8 you keep asking him questions
9 about areas that he's not going
10 into. I mean --
11 BY MR. DAVIS:
12 Q. You've reviewed the
13 nitrosamine testing data, have you not,
14 Dr. Sheinin? That's in your materials
15 considered list, is it?
16 MR. REEFER: Object to form.
17 Beyond the scope.
18 THE WITNESS: What are you
19 saying I reviewed?
20 BY MR. DAVIS:
21 Q. Your materials considered
22 list, Exhibit B, refers to you having
23 reviewed Mylan's nitrosamine testing data
24 for its valsartan products.

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1 Did you actually look at
2 that?
3 A. Are you referring to a
4 spreadsheet?
5 Q. Yes, I am.
6 A. I did see the spreadsheet.
7 Q. Okay. And did you see that
8 NDEA was present in every single line
9 there in that spreadsheet, every -- in
10 each line, representing a different lot
11 or batch of valsartan, that there was
12 NDEA in every single one of them? Did
13 you see that?
14 MR. REEFER: Object --
15 object to form. Mischaracterizes
16 the document.
17 Do you want to look at it,
18 John?
19 MR. DAVIS: He looked at it.
20 I'm entitled to ask him about it.
21 BY MR. DAVIS:
22 Q. Did you see the document?
23 You said you saw the
24 spreadsheet that had the nitrosamine

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1 testing data, that's right, Dr. Sheinin,
2 correct?
3 A. Correct.
4 Q. Okay. And did you see that
5 every single lot or batch on that
6 spreadsheet had NDEA in it?
7 A. I did not notice -- I did
8 not look at the entire spreadsheet, so I
9 can't say that yes or no, every single
10 lot had NDEA -- NDEA in it. I'd be happy
11 to look at it again.
12 Q. Do you think that -- do you
13 think that NDEA would have made it into
14 Mylan's valsartan products if they had
15 done a sound scientific appraisal of
16 their chemical manufacturing process?
17 MR. REEFER: Object to form.
18 Beyond the scope. Calls for
19 speculation. Foundation.
20 This is -- John, I'll just
21 let you know, this will be the
22 last question until -- you know, I
23 asked for a break 22 minutes ago.
24 And, you know, this is still going

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1 on.
2 So go ahead, Doctor.
3 THE WITNESS: That is not
4 something that I can answer. It's
5 organic chemistry, it's process
6 chemistry, and I can't say yes or
7 no. It's not within my -- the
8 expertise that I developed over
9 the last 50 years.
10 BY MR. DAVIS:
11 Q. It's in the FDA's warning
12 letter to Mylan, correct?
13 The FDA, in their warning
14 letter, said to Mylan that your firm had
15 not anticipated the creation of
16 nitrosamines in your drug product.
17 And that was the basis for
18 the warning letter, was that failure, was
19 it not?
20 MR. REEFER: Object to form.
21 Beyond the scope. Foundation.
22 Mischaracterizes the document.
23 THE WITNESS: FDA has said
24 that the formation of nitrosamines

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1 was unexpected. They did not see
2 it either. And they did a -- I
3 would hope, did a very thorough
4 review of the drug master file
5 that was submitted by Mylan. And
6 they did not see it.
7 So it's not something that I
8 would have seen, because it's
9 outside of my expertise. FDA did
10 not see it either, so --
11 BY MR. DAVIS:
12 Q. Okay. Well, you're
13 assuming --
14 A. -- it's not something --
15 Q. -- that Mylan disclosed all
16 the facts.
17 You're assuming there that
18 Mylan, in the DMF, actually disclosed the
19 salient information to the FDA, are you
20 not?
21 MR. REEFER: Object to form.
22 Beyond the scope. Argumentative.
23 Foundation.
24 He's not reviewed the DMF.

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1 He's not offering an opinion on
2 the content of the DMF, whether
3 Mylan's risk evaluation was --
4 MR. DAVIS: Hang on, Jason.
5 MR. REEFER: -- or
6 otherwise.
7 MR. DAVIS: Stop with the
8 speaking objections. He's brought
9 up that the FDA didn't see it
10 either. I'm entitled to ask about
11 that.
12 BY MR. DAVIS:
13 Q. And my question about that,
14 Dr. Sheinin, is, you're making an
15 assumption there that the FDA had the
16 same information in their hands that
17 Mylan did, right, based on what was in
18 the DMF?
19 MR. REEFER: Objection.
20 Foundation. Form. Can't speak to
21 what FDA knew or didn't know.
22 Go ahead, Doctor, if you
23 can.
24 THE WITNESS: I mean, I have

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1 not seen the DMF, so I don't know
2 what was in it.
3 I -- maybe I'm naive, but I
4 did not -- when I was at FDA, I
5 did not make an assumption that
6 companies that submitted drug
7 master files were not telling me
8 the truth. So I'm at a loss
9 there.
10 It's -- I don't know what
11 was in the DMF, so I don't know
12 exactly what FDA reviewed. But
13 FDA has said in several of their
14 statements on nitrosamines that
15 the presence of nitrosamines was
16 unexpected. So it goes beyond
17 Mylan, it goes to all the
18 companies who were making similar
19 types of APIs. The FDA has said
20 this was totally unexpected. And
21 I believe the EMA has said the
22 same thing, that it was
23 unexpected.
24 MR. REEFER: With that said,

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1 John --
2 MR. DAVIS: Last question --
3 last question before lunch.
4 BY MR. DAVIS:
5 Q. You said that, you know, you
6 had a right, when you were at FDA, to
7 assume what was being provided to you was
8 the truth, correct?
9 A. I didn't say it was a right.
10 I said that was me, as Eric Sheinin,
11 assuming that what was in the DMF was the
12 truth.
13 Q. That's a fair --
14 MR. REEFER: So, John --
15 BY MR. DAVIS:
16 Q. That's a fair --
17 MR. REEFER: John, hold on.
18 BY MR. DAVIS:
19 Q. -- and reasonable assumption
20 to make, right?
21 MR. REEFER: Hold on.
22 John, you said last question
23 and, you know. That was your last
24 question.

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1 MR. DAVIS: Let me -- let me
2 tie a bow on it.
3 BY MR. DAVIS:
4 Q. That was a fair and
5 reasonable assumption for someone in your
6 shoes at the FDA to make, that the DMF
7 that was being provided to them was the
8 truth, was transparent, correct?
9 MR. REEFER: Object to form.
10 Beyond the scope.
11 Go ahead, Dr. Sheinin, if
12 you want.
13 THE WITNESS: Yes. That was
14 my assumption. And I would think
15 that when FDA investigators come
16 in to the facility and are doing
17 an inspection to make sure that
18 the manufacturer is performing the
19 synthetic scheme to what's in the
20 drug master file that they would
21 be viewing whether or not the
22 processes that are being used to
23 manufacture and synthesize the
24 active ingredient are what's

<p>Page 170</p> <p>1 included in the drug master file. 2 If there was any 3 discrepancies, I would expect an 4 FDA investigator to note them. 5 MR. REEFER: So with that 6 being said, John, how long do you 7 need for lunch? And sort of let's 8 talk planning a little bit. 9 MR. DAVIS: We can go off 10 the record. 11 VIDEO TECHNICIAN: Going off 12 the record. The time is 1:17 p.m. 13 - - - 14 (Whereupon, a luncheon 15 recess was taken.) 16 - - - 17 VIDEO TECHNICIAN: We are 18 back on the record. The time is 19 2:19 p.m. 20 BY MR. DAVIS: 21 Q. Okay. Dr. Sheinin, I'm 22 going to mark Tab 5. 23 - - - 24 (Whereupon, Exhibit</p>	<p>Page 172</p> <p>1 files? 2 A. I don't think that the -- 3 whatever information that was in there 4 was really pertinent to my discussion of 5 drug master files in my report. I wasn't 6 going to be opining on the adequacy of 7 Mylan's DMF. 8 So in the interest of the 9 time that I had to devote to this 10 project, if I had gotten involved in 11 really looking at the DMF, I probably 12 would have just wanted to keep going and 13 going. 14 So it just -- it wasn't 15 necessary for what I was asked to look 16 at. 17 Q. Well, let me direct your 18 attention, then, before we turn to 19 Exhibit-10, back to your report for a 20 second. 21 I just want to get 22 clarification on what you mean in 23 Paragraph 68 of your report where you 24 write, Mylan's valsartan USP API</p>
<p>Page 171</p> <p>1 Sheinin-10, 2 MYLAN-MDL2875-00894833, Valsartan 3 Drug Master File, Section 3.2.S.3, 4 was marked for identification.) 5 - - - 6 BY MR. DAVIS: 7 Q. Let me know when you have 8 that document in front of you. 9 MR. REEFER: And I think, 10 John, this is 10, Exhibit-10, that 11 is. 12 MR. DAVIS: Exhibit-10, 13 that's right. 14 THE WITNESS: I have it. 15 BY MR. DAVIS: 16 Q. Okay. Let me ask a 17 prefatory question. 18 You told me you did not 19 review any aspect of Mylan's DMF; is that 20 right? 21 A. That is correct. 22 Q. Can I ask why, given that 23 you have an entire section of your report 24 dedicated to discussing drug master</p>	<p>Page 173</p> <p>1 continued to meet its specification, as 2 well as it's DMF specification, 3 throughout this period. 4 What are you -- what do you 5 mean by "DMF specification" there? 6 A. By DMF specification I mean 7 what was on file with the FDA. 8 Q. Okay. But you didn't review 9 the DMF? 10 A. That's correct. But I did 11 look at certificates of analysis, so I 12 could see that Mylan was in compliance 13 with all of the acceptance criteria in 14 the DMF. 15 Q. So what is -- is a DMF 16 specification similar to a USP 17 specification, it just has a test 18 procedure laid forth, basically? 19 A. A DMF specification is, 20 basically, the same specification that's 21 in the ANDA. Because that's where the 22 specification comes from, since Mylan is 23 using a drug master file to report that 24 information to FDA.</p>

<p style="text-align: right;">Page 174</p> <p>1 So that means that the DMF 2 specification has more in it than what's 3 in the USP monograph. 4 Q. Okay. 5 A. Because the application 6 specification is the same as the DMF 7 specification, and that has additional 8 tests in it. 9 Q. Is the DMF specification 10 sort of the final output of the ANDA DMF? 11 A. I don't understand that 12 question. I'm not clear. 13 Q. Sure. 14 There might be -- for 15 example, let's take a category of 16 testing, like residual solvent testing, 17 that's in the DMF specification. 18 There's a lot of workup in 19 the DMF regarding what to test for that's 20 ultimately put in the DMF specification, 21 is it not -- is there not? 22 A. That's correct. 23 Q. So the DMF specification, 24 ultimately, is an output of all of the</p>	<p style="text-align: right;">Page 176</p> <p>1 documented? 2 A. Well, part of the work 3 that's in the specification is the 4 analytical methods. And that's -- that's 5 done in Section 4.2 of the application. 6 And Section 4.3 is the validation of the 7 analytical method. 8 So that -- that's -- that 9 has to be done before you can have a 10 specification. 11 Q. And where -- where is that 12 work documented? It's documented in the 13 DMF, is it not? 14 A. The method validation work 15 is -- should be documented in the drug 16 master file. So those -- the method 17 validation for each one of the analytical 18 procedures that's used to control the 19 quality of the product should be included 20 in the drug master file. 21 Q. Okay. Back to Exhibit-10, 22 which I just marked. 23 Do you recognize that as the 24 impurities section of the valsartan drug</p>
<p style="text-align: right;">Page 175</p> <p>1 work that's done in the DMF itself, 2 right? 3 A. Yes and no. I mean, there's 4 other information in the DMF that has 5 nothing to do with the specification. 6 Q. Sure. But what's in the 7 specification is an output of what's -- 8 of the work that's done in the DMF, is it 9 not? 10 A. I've never heard it 11 expressed in that way. It's the -- the 12 specification is what FDA says you have 13 to meet, your specification. 14 And, in general, what's in 15 the USP monograph is in agreement with 16 the part of the specification that those 17 tests are included in. 18 Q. You wouldn't just write a 19 DMF specification, would you? There's 20 quite a bit of work that goes into 21 generating a DMF specification, right? 22 A. Well, yeah. Yeah. Of 23 course. 24 Q. And where is that work</p>	<p style="text-align: right;">Page 177</p> <p>1 master file? 2 A. No, I've never seen this, 3 because I didn't look at the drug master 4 file. 5 Q. Right. I understand that 6 you haven't seen this in particular. 7 But you've seen drug master 8 files generally, correct? 9 A. Yes. 10 Q. And a drug master file will 11 have an impurities section, will it not? 12 A. It should have an impurities 13 section, yeah. 14 Q. Okay. And does what I've 15 marked here as Exhibit-10 look like that 16 might be the impurities section of 17 Mylan's valsartan USP drug master file? 18 A. It looks like it. 19 Q. Okay. And you'll see on 20 the -- there's some numbering in the 21 bottom right corner, starting on the 22 second page. 23 A. Page numbers? 24 Q. That's correct.</p>

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1 Do you see that?

2 A. Yes.

3 Q. At the first numbered page,

4 you'll see a table of contents for this

5 DMF impurities section.

6 Do you see that?

7 A. Yes.

8 Q. And then at the very end, at

9 Pages 80 to 82, there's a section on

10 genotoxic impurities.

11 Do you see that?

12 A. Yes.

13 Q. Why are genotoxic impurities

14 broken out as a separate category of

15 impurities, do you know?

16 MR. REEFER: Object to form.

17 Scope.

18 THE WITNESS: I don't know.

19 BY MR. DAVIS:

20 Q. Okay.

21 A. I've not seen them --

22 anything that I have looked at, at FDA or

23 USP, where genotoxic impurities were

24 broken out as a separate category of

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1 impurities.

2 I know impurities, I know

3 inorganic impurities, residual solvents

4 are basically organic impurities, but

5 they are oftentimes categorized different

6 because there's a separate analytical

7 method. And I have never seen a list

8 like this that had genotoxic impurities

9 as a category.

10 Q. You don't think that would

11 be because there's separate applicable

12 guidances that govern genotoxic

13 impurities, such as, for example, ICH M7

14 that I've shown you today?

15 MR. REEFER: Objection.

16 Form and scope.

17 THE WITNESS: It's possible,

18 but I can't say yes or no. I

19 don't -- I don't know.

20 BY MR. DAVIS:

21 Q. Flip, if you would, to the

22 very last two pages of this document,

23 which are numbered 81 and 82.

24 A. Okay.

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1 Q. Do you see the header at the

2 top of Page 81, Genotoxic Impurities?

3 A. Yes.

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 [REDACTED]

20 [REDACTED]

21 [REDACTED]

22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

Page 181

1 [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 [REDACTED]

20 [REDACTED]

21 [REDACTED]

22 [REDACTED]

23 MR. DAVIS: I'm going to

24 mark Tab 24.

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1 MR. REEFER: Can we put this
2 away?
3 MR. DAVIS: Yes. Tab 24,
4 Jason.
5 MR. REEFER: Is that one
6 that you sent today or --
7 MR. DAVIS: Yes, that's one
8 sent today.
9 MR. REEFER: What's the
10 one -- which one did you send me
11 at lunch? Is that the one or is
12 that --
13 MR. DAVIS: That's 25.
14 MR. REEFER: Okay. Just one
15 moment, then, okay, John?
16 - - -
17 (Whereupon, Exhibit
18 Sheinin-11,
19 MYLAN-MDL2875-00392350, 11/26/18
20 E-mail, Owens to Smith, was marked
21 for identification.)
22 - - -
23 MR. REEFER: They're not
24 stapled, but I think that we

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1 should be able to make due. So
2 I'm going to hand it to him now,
3 okay, John.
4 MR. DAVIS: Sure.
5 BY MR. DAVIS:
6 Q. You'll see, Dr. Sheinin,
7 that this is an internal -- or partly
8 internal Mylan e-mail chain that has a
9 Plaintiff Owens-2 sticker on it.
10 MR. REEFER: I'm going to
11 object initially to foundation.
12 Is this Exhibit-11 marked,
13 John?
14 MR. DAVIS: Yes, it is.
15 MR. REEFER: Thanks. But I
16 object to foundation.
17 But go ahead, Dr. Sheinin.
18 BY MR. DAVIS:
19 Q. Sure. And I'm just making a
20 representation to you here, Dr. Sheinin,
21 I understand that you haven't seen this
22 document before.
23 I'm representing this to you
24 to be a partly internal Mylan e-mail

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1 chain with a Mylan Bates stamp, as it was
2 produced to us, dated November 2018.
3 Do you see that?
4 A. Yes.
5 Q. And I say "partly internal,"
6 because if you go down to the second and
7 third e-mails, there are some FDA e-mail
8 addresses on the e-mails, including for
9 Ms. Dellarese Herbert.
10 Do you see that?
11 A. Yes.
12 Q. Okay. And you'll see on the
13 second page of the e-mail chain, there's
14 an e-mail from Dellarese Herbert at FDA
15 to several Mylan individuals that's dated
16 November 19, 2018.
17 Do you see that?
18 MR. REEFER: Let me, just
19 for a moment, Eric, object. I'll
20 object on foundation.
21 But based on your prior
22 representation about who is on the
23 e-mail recipients, I'll let him
24 answer, okay, John?

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1 Do you understand what I'm
2 saying?
3 MR. DAVIS: Sure. Yeah.
4 MR. REEFER: Yeah. My point
5 being I don't think that
6 Dr. Sheinin knows exactly who
7 these people are. But your
8 representation being that those
9 are Mylan employees, with that
10 said, I'll let him go, okay?
11 MR. DAVIS: Sure. And I'm
12 happy to ask about e-mail
13 addresses.
14 BY MR. DAVIS:
15 Q. Do you see some FDA e-mail
16 addresses and some Mylan.com e-mail
17 addresses on that particular e-mail at
18 the top of Page 2?
19 A. Yes.
20 Q. And the from e-mail address,
21 it's dellarese.herbert@fda.hhs.gov.
22 Do you see that?
23 A. Yes.
24 Q. And there's several Mylan

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1 individuals listed in the to and cc
2 section.
3 Do you see that?
4 MR. REEFER: Same objection.
5 THE WITNESS: Yes.
6 BY MR. DAVIS:
7 Q. Including a Ms. Cassandra
8 Bird.
9 Is that a name you
10 recognize?
11 A. No.
12 Q. So you wouldn't know that
13 she was deposed in this case and that --
14 and that there would have been a
15 transcript of her deposition prepared?
16 A. I don't know that she was
17 deposed. I don't know who she is. I
18 have not seen a deposition from her. I
19 just don't know anything about her.
20 Q. Right. And that's because
21 it wasn't provided to you by counsel in
22 the package, right?
23 MR. REEFER: Object to form.
24 THE WITNESS: Correct.

Page 187

1 BY MR. DAVIS:
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 BY MR. DAVIS:
22 Q. Okay.
23 MR. DAVIS: I'm going to
24 mark Tab 23 as Exhibit-12.

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1 - - -
2 (Whereupon, Exhibit
3 Sheinin-12,
4 MYLAN-MDL2875-00552465, DMF DLAPI
5 Information Request, was marked
6 for identification.)
7 - - -
8 MR. REEFER: Should we put
9 it away, John, or keep it handy?
10 MR. DAVIS: We can put it
11 away.
12 MR. REEFER: Okay. So now
13 you want 23. What's on the front
14 page, John? I'm trying to leaf
15 through this.
16 MR. DAVIS: Plaintiff
17 Talton-7 is the exhibit stamp.
18 MR. REEFER: Okay. Thanks.
19 THE WITNESS: This is going
20 to be 12; is that right?
21 MR. DAVIS: Exhibit-12,
22 that's correct.
23 BY MR. DAVIS:
24 Q. And I only am going to show

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1 you this for a limited reason,
2 Dr. Sheinin. So don't fret, I'm not
3 going to make you look at all 100 pages
4 of it.
5 So you'll see --
6 A. Thank you.
7 Q. -- in the first -- the first
8 actual page -- a lot of these documents
9 come with a slip page at the front, which
10 is just what's called metadata regarding
11 the document that is as it was produced
12 by Mylan.
13 But you'll see the first
14 actual page, there's a letter from the
15 FDA to Mylan, attention Michael Plastina.
16 Do you see that?
17 A. Yes.
18 Q. And it says, This
19 communication is in reference to your
20 drug master file for valsartan.
21 Do you see that?
22 A. Yes.
23 Q. Okay. If you flip to the
24 next page, Page 2, you'll see the actual

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1 information requests that start at the
2 very bottom, Numbered 1, and then 1 has A
3 through J subparts that continue on the
4 next pages.
5 Do you see that?
6 A. Yeah.
7 I was looking for the date
8 of this letter.
9 Q. I can help you with that.
10 A. It's usually at the end.
11 MR. REEFER: It's November
12 13th, 2018. Is that what you were
13 going to say, John?
14 MR. DAVIS: Yes.
15 BY MR. DAVIS:
16 Q. That's on Page 7.
17 MR. REEFER: Dr. Sheinin, if
18 you need to take a moment to
19 familiarize yourself with the
20 document, you're entitled to do
21 so.
22 BY MR. DAVIS:
23 Q. Do you see the date stamp,
24 Dr. Sheinin, that appears after David

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1 Skanchy's signature?
2 A. Yes.
3 Q. And that date is November
4 13th, 2018?
5 A. Yes.
6 Q. What's your understanding
7 of -- what's your understanding of
8 where --
9 A. I was going to say --
10 Q. -- where that date falls in
11 the chronology of Mylan's valsartan
12 recall?
13 A. I'm not sure if it was
14 before or after the recall. But I think
15 it was -- this was after the recall, I
16 believe. But I'm -- I can't say for
17 sure.
18 Q. I'll represent to you that
19 Mylan's recall of all of its lots and
20 batches of valsartan on the market with
21 an expiry occurred in late November and
22 early December, after this letter --
23 A. Okay.
24 Q. -- if that gives you some

Page 192

1 context.
2 [REDACTED]

Page 193

1 [REDACTED]

<div>Page 194</div> <div>1 [REDACTED]</div>	<div>Page 196</div> <div>1 [REDACTED]</div>
<div>Page 195</div> <div>1 [REDACTED]</div>	<div>Page 197</div> <div>1 [REDACTED]</div>

<div>Page 198</div> <div>1</div> <div></div>	<div>Page 200</div> <div>1</div> <div>2</div> <div></div>
<div>Page 199</div> <div></div>	<div>Page 201</div> <div>1</div> <div></div>

Page 202

1 [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 MR. DAVIS: Let's mark Tab

7 25 as Exhibit-13.

8 - - -

9 (Whereupon, Exhibit

10 Sheinin-13, No Bates, Valsartan

11 Development Report, Addendum IV,

12 was marked for identification.)

13 - - -

14 MR. REEFER: Should we put

15 12 aside, John?

16 MR. DAVIS: Yes, you may.

17 MR. REEFER: Okay. And 25

18 is the new one, right --

19 MR. DAVIS: That's correct.

20 MR. REEFER: -- that you

21 sent during lunch?

22 Okay. Thank you.

23 BY MR. DAVIS:

24 Q. Did you review any

Page 203

1 development reports related to Mylan's

2 development of its manufacturing process

3 for valsartan API, Dr. Sheinin?

4 A. Not that I'm aware of. I

5 don't believe I reviewed any development

6 reports.

7 Q. You'll see some numbering,

8 C01, C02, C03, it's kind of like stamped

9 numbering in the bottom center of the

10 pages.

11 A. Yeah. Some of them are

12 rather blurry. But I can see there's

13 numbers or something down there.

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 [REDACTED]

20 [REDACTED]

21 [REDACTED]

22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

Page 204

1 [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 Q. Did you -- in preparing your

19 expert report, Dr. Sheinin, did you come

20 to any kind of understanding of how NDEA

21 was formed exactly in Mylan's valsartan

22 API?

23 MR. REEFER: Object to form.

24 Scope and foundation.

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1 But go ahead, Doctor, if you

2 know.

3 THE WITNESS: I did not come

4 to any conclusion on that. I

5 wasn't asked to look into it.

6 BY MR. DAVIS:

7 Q. Even though you weren't

8 asked to look into it, do you have at

9 least some kind of understanding of how

10 it formed?

11 MR. REEFER: Same objection.

12 Asked and answered.

13 THE WITNESS: I have some

14 understanding, but I don't know

15 the -- all the conditions and what

16 it takes to form NDEA.

17 BY MR. DAVIS:

18 Q. Dr. Daniel Snyder's

19 deposition testimony and exhibits are

20 listed in your Exhibit B, materials

21 considered, are they not?

22 A. I see a Dan Snyder, yes. I

23 did not look at his report.

24 Q. Well, he's a -- he was a

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1 Mylan fact witness deposition that was
2 taken in this case. So he wouldn't have
3 prepared an expert report. However, his
4 testimony largely centered on Mylan's
5 root cause evaluation.
6 Do you recall reading his
7 testimony?
8 A. I did not read it.
9 Q. Did you look at any of the
10 exhibits to his deposition?
11 A. I don't know anything about
12 him. I didn't look at it.
13 I think I mentioned earlier
14 all those individuals listed at the end
15 of my list, I did not look at any of
16 their information, reports or depositions
17 or anything.
18 Q. So it was provided to you
19 but you didn't look at it?
20 A. Correct.
21 Q. Okay. What I've marked as
22 Exhibit-13 here, which is Addendum IV to
23 the valsartan development report, that's
24 also listed in your Exhibit B, materials

Page 207

1 considered, is it not?
2 MR. REEFER: I'm sorry,
3 John, the correct -- I think you
4 said, maybe, the wrong exhibit
5 number. Or did I write it down
6 wrong?
7 Oh, I'm sorry. I'm so
8 sorry, John, I interrupted you. I
9 messed up. I wrote down
10 Exhibit-25 because it was Tab 25.
11 I'm sorry to interrupt your
12 examination, John.
13 MR. DAVIS: Not a problem.
14 BY MR. DAVIS:
15 Q. So the question,
16 Dr. Sheinin, is what I've marked as
17 Exhibit-13, which is the 70-page document
18 entitled, Addendum IV to Valsartan
19 Development Report, that's also listed in
20 your materials considered, is it not,
21 under Item 8?
22 A. Yes.
23 Q. Did you review this?
24 A. No.

Page 208

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

Page 209

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 BY MR. DAVIS:
18 Q. Let me ask you, Dr. Sheinin,
19 from a -- from a process chemistry
20 perspective, would you assume a different
21 result, in terms of chemical reactions,
22 if the same process was followed every
23 single time?
24 MR. REEFER: Object to

<p>Page 210</p> <p>1 foundation and scope.</p> <p>2 THE WITNESS: And I'm not a</p> <p>3 process chemist, but my experience</p> <p>4 has been that when you're</p> <p>5 manufacturing batch after batch</p> <p>6 after batch of a drug substance,</p> <p>7 you're not going to end up with</p> <p>8 exactly the same impurity profile</p> <p>9 and you're not going to end up</p> <p>10 with exactly the same assay value.</p> <p>11 So I wouldn't want to say</p> <p>12 that everything is going to be</p> <p>13 exactly the same if you run the</p> <p>14 procedure the same way, with the</p> <p>15 qualification that I'm not a</p> <p>16 process chemist.</p> <p>17 BY MR. DAVIS:</p> <p>18 Q. But assuming -- let's assume</p> <p>19 that, you know, all of the -- all of the</p> <p>20 variables, meaning, like, the reagents,</p> <p>21 catalysts, the temperatures, the</p> <p>22 equipment used, all of those things are</p> <p>23 the same, chemical reactions don't choose</p> <p>24 to happen sometimes and not others,</p> <p>Page 211</p> <p>1 right?</p> <p>2 Isn't that a basic principle</p> <p>3 of organic chemistry, is that you can</p> <p>4 reliably cause chemical reactions to</p> <p>5 occur under certain conditions?</p> <p>6 MR. REEFER: Object to the</p> <p>7 scope. Foundation. Asked and</p> <p>8 answered.</p> <p>9 THE WITNESS: Again, when</p> <p>10 companies -- again, not being a</p> <p>11 process chemist, but companies are</p> <p>12 running their synthetic schemes, I</p> <p>13 would assume, the same way, and</p> <p>14 yet they can -- sometimes an</p> <p>15 impurity shows up, sometimes it's</p> <p>16 not.</p> <p>17 So it's not always going to</p> <p>18 be exactly the same even though</p> <p>19 they run the procedure the same</p> <p>20 way, use the same chemicals, the</p> <p>21 same reagents, the same</p> <p>22 temperatures, the same time.</p> <p>23 There is variation in what</p> <p>24 the results are.</p>	<p>Page 212</p> <p>1 BY MR. DAVIS:</p> <p>2 Q. Right. I'm asking more of a</p> <p>3 theoretical question, which is, isn't it</p> <p>4 a -- just a general principle of</p> <p>5 chemistry that if you -- that chemical</p> <p>6 reactions will occur in the way you would</p> <p>7 expect them to reliably?</p> <p>8 You don't mix two things and</p> <p>9 have a completely different result one</p> <p>10 time or another; chemical reactions occur</p> <p>11 reliably as a matter of the basic</p> <p>12 discipline of the science, correct?</p> <p>13 MR. REEFER: Object to form.</p> <p>14 Scope. Asked and answered again.</p> <p>15 THE WITNESS: In general,</p> <p>16 chemical reactions will go the</p> <p>17 same way. But there's</p> <p>18 different -- to a different</p> <p>19 extent, I have to go back to I'm</p> <p>20 not a process chemist, but when</p> <p>21 they run the procedure the same</p> <p>22 way, they are going to find</p> <p>23 differences. So it's not going to</p> <p>24 be exactly the same every time.</p> <p>Page 213</p> <p>1 BY MR. DAVIS:</p> <p>2 Q. You did say that you had</p> <p>3 reviewed the nitrosamine testing</p> <p>4 spreadsheet, correct?</p> <p>5 A. Yes.</p> <p>6 Q. And that did show NDEA</p> <p>7 present in every single lot batch that</p> <p>8 was tested, correct?</p> <p>9 A. I believe what I said was</p> <p>10 that I did not look at the entire</p> <p>11 spreadsheet, so I can't say that it was</p> <p>12 present in every single batch.</p> <p>13 But the page that I looked</p> <p>14 at, I did see it in those lots. But I</p> <p>15 did not look at the entire spreadsheet.</p> <p>16 MR. DAVIS: Hey, Jason,</p> <p>17 let's take a quick break, five</p> <p>18 minutes. I'm actually almost</p> <p>19 done, I just want to review my</p> <p>20 notes.</p> <p>21 MR. REEFER: No problem.</p> <p>22 VIDEO TECHNICIAN: Going off</p> <p>23 the record. The time is 3:13 p.m.</p> <p>24 - - -</p>
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1 (Whereupon, a brief recess
2 was taken.)
3 - - -
4 VIDEO TECHNICIAN: We are
5 back on the record. The time is
6 3:26 p.m.
7 BY MR. DAVIS:
8 Q. The last real item I want to
9 touch on, Dr. Sheinin, is your response
10 to Dr. Najafi's report.
11 That discussion appears at
12 Paragraphs 83 through, I guess, the end
13 of your report; is that right?
14 A. Basically, yeah, I think. I
15 don't think there's any other
16 subheadings.
17 Q. Can you describe to me
18 what -- what is your critique of
19 Dr. Najafi's report?
20 A. The main critique is that
21 he's saying that the impurity profile has
22 to be the same for the generic to be able
23 to say that the API is the same as is
24 used in the reference-listed drug.

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1 And I believe I go on to
2 discuss why that's not the case. And,
3 again, I would come back to the fact that
4 when a company makes the drug substance
5 by one route and a second company is
6 making it by a different route, you're
7 going to get, almost for certain, a
8 different impurity profile, and, still,
9 under the definition in the regulations,
10 those two APIs are the same.
11 The impurity profile is
12 immaterial to whether or not the API is
13 the same as what's in the
14 reference-listed drug. And he doesn't
15 seem to agree with that.
16 Q. Well, he also doesn't say
17 that, though, does he? He doesn't say
18 anywhere in his declaration that the
19 impurity profiles generally have to be
20 the same, does he?
21 A. From what I remember, he's
22 saying that the impurity profiles have to
23 be the same or it's not considered to be
24 the same API.

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1 Q. But you can't point me to a
2 particular portion of his report you're
3 referring to where you claim that he says
4 that?
5 A. I don't have it in front of
6 me, and I'd have to read through his
7 report again.
8 But that's -- that's my
9 understanding and impression, was that he
10 was saying that they're not the same
11 because they have different impurity
12 profiles.
13 Q. You don't cite the portion
14 of his report you're claiming where he
15 says that in your -- in your report, do
16 you?
17 A. I don't -- I don't think so.
18 Q. Okay. So the answer is no?
19 A. 98, Dr. Najafi concludes
20 that valsartan-containing products that
21 contained NDMA and NDEA were not the
22 generic equivalent of Diovan or Exforge
23 because they contained NDMA and NDEA.
24 And what I'm saying is the

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1 drug substance used in Mylan's valsartan,
2 by the definition in the regulations, is
3 the same as the valsartan that's used in
4 the innovator product. But he's saying
5 they're not, and I'm saying that they
6 are.
7 Q. Well, what's your basis for
8 saying that they are, despite the fact
9 that they had NDMA and NDEA and were all,
10 by the way, recalled?
11 A. The basis for what I'm
12 saying is that, as I stated a little bit
13 ago, you can have different impurity
14 profiles in the active ingredient and
15 it's still considered the same as that
16 that's used in the reference-listed drug.
17 That's what the regulations
18 describe, that the API is the same. The
19 impurity profile is immaterial to that,
20 unless -- unless you have a case where
21 there's an impurity that makes up 50
22 percent of the API.
23 I mean, you're not going to
24 have that, so --

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1 Q. So -- go ahead, Dr. Sheinin.
2 I didn't mean to cut you off.
3 A. The impurity profile is not
4 what determines whether the API is the
5 same in the reference-listed drug and the
6 generic drug.
7 Q. So let me get -- let me see
8 if I understand what you're saying.
9 You're saying, from a
10 general -- as a general proposition, it's
11 possible that an API can have a different
12 impurity profile and still be considered
13 a generic equivalent; is that what you're
14 saying?
15 A. I'm saying that the API can
16 have a different impurity profile and be
17 considered the same as the
18 reference-listed drug.
19 Q. And when you say "the
20 same" --
21 A. I'm saying that the API in a
22 generic drug can have a different
23 impurity profile and still be considered
24 the same as the API that's used in the

Page 219

1 reference-listed drug.
2 Q. Okay. And you're saying --
3 by "the same" -- what do you mean by "the
4 same" there?
5 A. That under the regulations
6 that it's considered the same ingredient
7 if it has the same structure, the same
8 purity -- I guess purity doesn't -- is
9 not really a factor.
10 But if it has the same
11 structure, if it's the same chemical,
12 then it's the same, regardless of what
13 its impurity profile is.
14 Q. Well, purity is a factor,
15 though.
16 What -- what regulations are
17 you referring to when you say that it
18 doesn't have to be -- that it is the same
19 regardless of the impurity profiles?
20 What regulation are you referring to for
21 your understanding of that?
22 A. I'd have to go back into the
23 CFR. It could be in a guidance. But
24 it's --

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1 Q. Are you familiar with the
2 FDA's Orange Book?
3 A. Yes.
4 Q. You don't mention the Orange
5 Book anywhere in your report, do you?
6 A. No, I do not.
7 Q. And it's not listed in your
8 materials considered, is it?
9 A. It is not.
10 Q. Okay. When is the last time
11 you think you reviewed the -- anything
12 regarding the FDA's Orange Book?
13 A. It was at some point this
14 year that I can remember looking --
15 looking at the Orange Book.
16 Q. In your understanding, what
17 is the FDA Orange Book?
18 A. The Orange Book is --
19 MR. REEFER: Objection to
20 scope.
21 THE WITNESS: Sorry.
22 MR. REEFER: Go ahead.
23 THE WITNESS: The Orange
24 Book is a -- basically a

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1 compendium of all the products
2 that are approved by FDA, and
3 they're listed by active
4 ingredient.
5 And it shows whether or not
6 a generic is considered
7 bioequivalent to the
8 reference-listed drug, and it
9 shows which -- which product or
10 products are considered as
11 reference-listed drugs.
12 BY MR. DAVIS:
13 Q. Well, bioequivalence is just
14 one aspect of therapeutic equivalence,
15 right, which is the larger thing the
16 Orange Book is concerned with, correct?
17 A. I believe so.
18 Q. And the Orange Book will
19 list, like you say, various drugs and
20 which ones are therapeutically
21 interchangeable with each other because
22 of a therapeutic equivalence
23 determination, correct?
24 MR. REEFER: Object to form.

<p>Page 222</p> <p>1 Scope.</p> <p>2 THE WITNESS: Correct.</p> <p>3 MR. DAVIS: Let me mark Tab</p> <p>4 17 as Exhibit-14.</p> <p>5 - - -</p> <p>6 (Whereupon, Exhibit</p> <p>7 Sheinin-14, No Bates, Orange Book</p> <p>8 Preface, Food and Drug</p> <p>9 Administration, Center for Drug</p> <p>10 Evaluation and Research, Approved</p> <p>11 Drug Products with Therapeutic</p> <p>12 Equivalence Evaluations, was</p> <p>13 marked for identification.)</p> <p>14 - - -</p> <p>15 BY MR. DAVIS:</p> <p>16 Q. Have you read this</p> <p>17 FDA-authored Orange Book preface before,</p> <p>18 Dr. Sheinin?</p> <p>19 A. No, I have not.</p> <p>20 Q. Do you see that the URL at</p> <p>21 the bottom of the page is pulled from the</p> <p>22 www.fda.gov website?</p> <p>23 A. Yes.</p> <p>24 Q. And you'll see on the second</p> <p>Page 223</p> <p>1 page, bottom -- bottom two paragraphs,</p> <p>2 really, the FDA says that, The</p> <p>3 therapeutic equivalence evaluations in</p> <p>4 the Orange Book reflect the FDA's</p> <p>5 application of specific criteria to the</p> <p>6 multi-source prescription drug products</p> <p>7 listed in the Orange Book and approved</p> <p>8 under the FD&C Act.</p> <p>9 Do you see that?</p> <p>10 A. Yes.</p> <p>11 Q. And then the next paragraph</p> <p>12 down says that, A complete discussion of</p> <p>13 the background and basis of the FDA's</p> <p>14 therapeutic equivalence evaluation policy</p> <p>15 was published in the Federal Register in</p> <p>16 1979.</p> <p>17 Do you see that?</p> <p>18 A. Yes.</p> <p>19 Q. If you go to Page 4, you'll</p> <p>20 see a section titled, Introduction.</p> <p>21 A. Yes.</p> <p>22 Q. It says, The Orange Book is</p> <p>23 composed of four parts.</p> <p>24 And the first part is,</p>	<p>Page 224</p> <p>1 Approved prescription drug products with</p> <p>2 therapeutic equivalence evaluations.</p> <p>3 Do you see that?</p> <p>4 A. Can you read that again?</p> <p>5 Q. The first sentence of the</p> <p>6 introduction reads, The Orange Book is</p> <p>7 composed of four parts.</p> <p>8 And then the first part it</p> <p>9 lists is, Approved prescription drug</p> <p>10 products with therapeutic equivalence</p> <p>11 evaluations.</p> <p>12 Do you see that?</p> <p>13 A. Yes.</p> <p>14 Q. Okay.</p> <p>15 A. I see that.</p> <p>16 Q. So would you agree that</p> <p>17 therapeutic equivalence is really the</p> <p>18 regulatory touchstone of evaluating</p> <p>19 whether a generic product is -- can be</p> <p>20 considered the same as a brand product?</p> <p>21 MR. REEFER: Object to form.</p> <p>22 Scope.</p> <p>23 THE WITNESS: I would say</p> <p>24 that therapeutic equivalence,</p> <p>Page 225</p> <p>1 if -- if the generic is</p> <p>2 therapeutically equivalent to the</p> <p>3 reference-listed drug, that</p> <p>4 they're interchangeable.</p> <p>5 BY MR. DAVIS:</p> <p>6 Q. And that's the FDA's way of</p> <p>7 saying you can -- you can take it to the</p> <p>8 bank that this drug is going to be the</p> <p>9 same as the RLD, correct?</p> <p>10 MR. REEFER: Object to form.</p> <p>11 Vague.</p> <p>12 THE WITNESS: My -- my way</p> <p>13 of looking at it is if FDA has</p> <p>14 approved a generic drug and FDA</p> <p>15 says it's therapeutically</p> <p>16 equivalent, that I can take the</p> <p>17 generic in lieu of taking the</p> <p>18 reference-listed drug to achieve</p> <p>19 the desired outcome for whatever</p> <p>20 reason that I'm taking the drug</p> <p>21 for.</p> <p>22 BY MR. DAVIS:</p> <p>23 Q. And that's what's most</p> <p>24 important here, right, for physicians'</p>
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1 and patients' purposes in evaluating
2 whether a generic is the same as the
3 brand, right?
4 It's not living in some
5 hypothetical world, it's -- there's a
6 reason for that, which is, can I
7 substitute it for the brand, right?
8 MR. REEFER: Object to form.
9 Scope. Foundation.
10 THE WITNESS: Yeah. The --
11 again, to me, the generic means
12 that the FDA has approved it and
13 it's therapeutically equivalent,
14 so I have no problem with taking
15 the generic in lieu of taking a
16 reference-listed drug.
17 BY MR. DAVIS:
18 Q. And that's what it means to
19 be -- sorry. Go ahead.
20 A. I was going to say, the
21 issue of sameness, we were discussing
22 sameness of the active ingredient. I
23 don't know that that's exactly the same
24 as the sameness of whether it's

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1 therapeutically equivalent or not.
2 It's two different -- to me,
3 it's two different uses of "sameness."
4 Q. Okay. And you're not sure
5 what Dr. Najafi was referring to in his
6 report, whether he was referring to the
7 defendants at issue, VCDs being
8 therapeutic equivalents or generic
9 equivalents or whether the API was just
10 the same, are you?
11 A. He's saying
12 valsartan-containing drug products that
13 contain NDMA and NDEA were not the
14 generic equivalent of Diovan or Exforge
15 because they contained NDMA and NDEA.
16 So I'm saying that they are
17 equivalent.
18 Q. You're saying that they're
19 therapeutically equivalent under the
20 Orange Book?
21 A. Yes.
22 Q. But you haven't looked at
23 the Orange Book at all in your report,
24 have you?

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1 A. No, I have not.
2 Q. Okay. And you're just now
3 looking at the Orange Book preface since
4 I've showed it to you, correct?
5 A. Correct.
6 Q. So is this, like, an
7 off-the-cuff opinion that you're making?
8 MR. REEFER: Object to form.
9 Argumentative.
10 MR. DAVIS: Well, no, it's a
11 fair question.
12 BY MR. DAVIS:
13 Q. Dr. Sheinin, you don't --
14 you don't put anywhere in your report the
15 opinion that the NDMA- and
16 NDEA-contaminated valsartan is a
17 therapeutic equivalent to the RLD, do
18 you? That's nowhere in your report, is
19 it?
20 A. No.
21 Q. Okay. And do you know what
22 criteria, even, the FDA requires for a
23 drug to be considered therapeutically
24 equivalent to an RLD?

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1 MR. REEFER: Object to form.
2 Foundation.
3 Go ahead.
4 THE WITNESS: I know it has
5 to be considered to be
6 bioequivalent. I'm not sure what
7 the second criteria is. I know
8 that there's two factors that go
9 into the therapeutic equivalence.
10 BY MR. DAVIS:
11 Q. So how could you form an
12 opinion that the defendants' valsartan in
13 this case was therapeutically equivalent
14 to the RLD when you're not sure what the
15 definition of therapeutic equivalence is?
16 MR. REEFER: Object to form.
17 Misstates testimony. Beyond the
18 scope.
19 THE WITNESS: What exactly
20 did I say?
21 Najafi said that if it
22 contains NDMA and NDEA, that it's
23 not the generic equivalent. I did
24 not use the words "therapeutically

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1 equivalent."
2 And, to me, the fact that
3 NDMA and NDEA may be present does
4 not make it not generically
5 equivalent to the reference-listed
6 drug.
7 It's the active ingredient
8 that's important. The impurities
9 in general do not contribute to
10 the efficacy of the active
11 ingredient and the drug product.
12 So the presence of impurities is
13 immaterial to whether or not the
14 generic is equivalent to the
15 reference-listed drug.
16 BY MR. DAVIS:
17 Q. Well, the FDA is not just
18 concerned with efficacy, they're also
19 concerned with safety, aren't they?
20 MR. REEFER: Object to form.
21 Beyond the scope.
22 THE WITNESS: They are. And
23 FDA has said that there is a
24 very -- what's the word I'm

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1 looking for -- theoretical issue
2 with nitrosamines and that there's
3 a very minimal risk and that these
4 impurities are present at
5 extremely low levels, they are
6 trace impurities. And there are
7 products that FDA has allowed on
8 the market that do contain
9 nitrosamines.
10 BY MR. DAVIS:
11 Q. I thought you told me you're
12 not a toxicologist, right, so you have no
13 way to independently evaluate any of
14 those assertions, right?
15 A. That's correct. I'm not a
16 toxicologist, but I can read what's
17 written in the FDA statements, that it's
18 a theoretical risk.
19 And it may -- I think it
20 says further in those statements that it
21 may be a cause of cancer; it may.
22 As a scientist, I don't have
23 to be a toxicologist to understand what
24 FDA is saying there.

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1 Q. The FDA did require the
2 recall of every single lot and batch of
3 Mylan's valsartan, did they not, though?
4 MR. REEFER: Objection to
5 form. Misstates facts. Beyond
6 the scope.
7 THE WITNESS: I believe
8 that, yes, FDA recalled all the
9 lots of Mylan's valsartan
10 products.
11 BY MR. DAVIS:
12 Q. And you're aware that the
13 IARC, EPA and other regulatory bodies
14 that evaluate toxicology have classified
15 NDMA and NDEA as probable human
16 carcinogens, correct?
17 MR. REEFER: Object to form.
18 Foundation. Beyond the scope.
19 MR. DAVIS: He's -- Jason,
20 he's the one who just brought this
21 up. I've got to delve into it
22 now.
23 MR. REEFER: He -- John, he
24 clarified that he was --

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1 MR. DAVIS: No, he didn't,
2 Jason. He went off on a tangent,
3 and now I've got to -- now I have
4 to put the lid back on it.
5 BY MR. DAVIS:
6 Q. So you can answer the
7 question, Dr. Sheinin.
8 Are you aware that the IARC,
9 EPA and other regulatory bodies governing
10 toxicology assessments have classified
11 NDMA and NDEA as probable human
12 carcinogens? Are you aware of that?
13 MR. REEFER: Object to form.
14 Foundation. Beyond the scope.
15 THE WITNESS: I know that
16 I -- IA-what -- IAR-whatever was
17 mentioned in the M7, I believe, in
18 that paragraph you had me look at.
19 But other than that, I don't
20 know anything else about that
21 organization or what EPA has said
22 or what any other organization has
23 said.
24 BY MR. DAVIS:

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1 Q. Are you aware that these
2 entities are so certain that NDMA and
3 NDEA are human carcinogens that it's
4 considered unethical to actually do the
5 studies to confirm that?
6 MR. REEFER: Object to form.
7 Sorry.
8 Object to form. Beyond the
9 scope. Foundation.
10 THE WITNESS: No, I'm not
11 aware.
12 BY MR. DAVIS:
13 Q. Okay. Are you aware that
14 Mylan's valsartan at times contained up
15 to 20 times what the FDA considers safe,
16 acceptable intakes for NDEA?
17 MR. REEFER: Object to form.
18 Misstates testimony and evidence.
19 But go ahead, Doctor.
20 THE WITNESS: I'm not aware
21 of -- I didn't do any calculations
22 to see how much above or below
23 the -- what FDA recommended.
24 That's all I can say.

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1 I did not do any kind of
2 calculation to determine that.
3 BY MR. DAVIS:
4 Q. Okay. Thank you.
5 So in Paragraph 99 of your
6 report, you say, As presented above,
7 valsartan manufactured by a different
8 route of synthesis that resulted in a
9 different impurity profile still would be
10 considered the same as that used in the
11 RLD.
12 Do you see that?
13 A. Yes, I see that.
14 Q. You're not saying there that
15 valsartan that contains NDMA and NDEA
16 would still be considered the same as
17 that -- as that used in the RDL, are you?
18 Is there a reason you're not
19 saying that -- is there -- let me strike
20 that and rephrase it.
21 Is there a reason that
22 Paragraph 99 reads the way it does as
23 opposed to stating the following, which
24 would be, valsartan that contains NDMA

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1 and NDEA would still be considered the
2 same as the RLD?
3 MR. REEFER: Object --
4 object to form. Vague.
5 But go ahead, Doctor, if you
6 understand.
7 THE WITNESS: That's the way
8 I always refer to the active
9 ingredient in a generic drug
10 versus the active ingredient in
11 the reference-listed drug.
12 To me, it's always the same.
13 If you have different routes of
14 synthesis, and even if you have a
15 different impurity profile, it's
16 still going to be the same active
17 ingredient.
18 BY MR. DAVIS:
19 Q. Well, the FDA, in that
20 situation, would have approved that
21 different route of synthesis, correct?
22 A. Correct.
23 Q. Okay. Have you seen any
24 evidence that the FDA approved valsartan

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1 products where there was an affirmative
2 disclosure that they contained NDMA and
3 NDEA?
4 MR. REEFER: Object to form.
5 Scope.
6 THE WITNESS: I have no way
7 to access whether or not there was
8 a valsartan that claimed to have
9 NDMA or NDEA in it and that
10 application was submitted to the
11 FDA and that it was approved. I
12 have no way of knowing that. So I
13 can't say if that's a possibility.
14 That information is
15 confidential and the FDA would not
16 release that. I don't have access
17 to FDA's information anymore.
18 BY MR. DAVIS:
19 Q. Is it your position that
20 purity has nothing to do with therapeutic
21 equivalence?
22 MR. REEFER: Object to form.
23 Misstates the testimony. Beyond
24 the scope.

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1 THE WITNESS: As long as the
2 drug substance meets the purity
3 acceptance criteria in the assay
4 in its specification, the purity
5 is going to vary for a number of
6 reasons.
7 And I don't believe that
8 that -- that a purity on one API
9 that was in the acceptance
10 criteria for the assay would be
11 considered not to be equivalent to
12 the reference-listed drug active
13 ingredient that had a different
14 assay value.
15 So there's -- that's why, in
16 many cases, the active ingredient
17 has an acceptance criteria of 98.0
18 to 102.0 percent.
19 BY MR. DAVIS:
20 Q. What about quality, is it --
21 do you have any understanding of whether
22 quality has anything to do with
23 therapeutic equivalence?
24 MR. REEFER: Object to form.

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1 Vague. Beyond the scope.
2 THE WITNESS: As long as the
3 generic or any -- any drug
4 substance meets the acceptance
5 criteria in the specification,
6 then -- and that includes not only
7 the assay but the impurity
8 testing, then I would consider
9 that to be the same as any other
10 API of that same chemical that has
11 also met the acceptance criteria
12 in the specification.
13 BY MR. DAVIS:
14 Q. Okay. Let me ask a
15 hypothetical to you, Dr. Sheinin.
16 The specification lists
17 impurities of not more than .1 percent in
18 this case, right, for valsartan? That's
19 what the specification says, right?
20 A. The specification for any
21 other unknown impurity is point -- not
22 more than .1 percent.
23 Q. Right. Let's say there was
24 some other unknown impurity that was

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1 guaranteed to kill anyone who ingested
2 the product at levels below .1 percent,
3 percent mortality rate, are you saying
4 that that would be considered the same,
5 from a purity or quality standpoint, as
6 the RLD?
7 MR. REEFER: Object to form.
8 Assumes facts. Incomplete
9 hypothetical.
10 Go ahead.
11 THE WITNESS: That's a very
12 hypothetical question that has no
13 place in the real world.
14 But in the specification, if
15 it's -- if it's -- has -- if it
16 meets the specification, then it's
17 the same.
18 BY MR. DAVIS:
19 Q. Okay.
20 A. You have to have other --
21 other testing and other things to come
22 into play for it to be considered not the
23 same.
24 Q. Okay. Turn to Page 7 of

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1 Exhibit-14, which is the FDA Orange Book
2 preface.
3 A. Okay.
4 Q. You'll see there's a
5 definition provided there for therapeutic
6 equivalence.
7 Do you see that?
8 A. Yes.
9 Q. And it says, FDA classifies
10 as therapeutically equivalent those drug
11 products that meet the following general
12 criteria.
13 Do you see that?
14 A. Yes.
15 Q. Okay. One, they are
16 approved as safe and effective.
17 Do you see that?
18 A. Yes.
19 Q. Do you know -- back to my
20 earlier question.
21 You don't know whether the
22 FDA has ever approved any valsartan drug
23 product -- or, rather, any product at all
24 that contains NDMA or NDEA as safe and

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1 effective, with the disclosure that it
2 actually contained NDMA or NDEA, correct?
3 A. I have no way of knowing
4 that.
5 Q. Do you have any
6 understanding of whether NDMA or NDEA
7 have any therapeutic benefit?
8 MR. REEFER: Object to form.
9 Foundation and scope.
10 But go ahead, if you know.
11 THE WITNESS: I don't know
12 whether they have any therapeutic
13 benefit. I -- I have not looked
14 into that.
15 I don't -- I don't believe
16 they act -- act to enhance the
17 therapeutic effect of the
18 valsartan, but I don't know what
19 their -- what could possibly be
20 their therapeutic benefit.
21 But I can't answer that
22 question. I don't know.
23 BY MR. DAVIS:
24 Q. Okay. The second criteria

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1 for meeting therapeutic equivalence is,
2 2, They are pharmaceutical equivalents in
3 that they contain identical amounts of
4 the identical active drug ingredient in
5 the identical dosage form and route of
6 administration.
7 Do you see that?
8 A. Yes.
9 Q. 2A?
10 A. I see that.
11 Q. Is that -- is that what
12 you're talking about when you're saying
13 that the API is the same because it meets
14 the spec? Are you saying that valsartan
15 API would be pharmaceutically equivalent
16 under 2A there?
17 A. I would say under 2B, Meet
18 compendial or other applicable standards
19 of strength, quality, purity and
20 identity.
21 If you take A and B
22 together, yes, that's what I'm saying.
23 Q. Okay. But you're -- you
24 conceded, though, that there are -- that

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1 other applicable standards out there
2 other than USP, correct? For example,
3 the ICH guidelines?
4 MR. REEFER: Object to form.
5 Misstates testimony.
6 THE WITNESS: ICH guidelines
7 do not set acceptance criteria for
8 any particular test --
9 BY MR. DAVIS:
10 Q. For ICH M7 it does, though.
11 We saw that in ICH M7.
12 ICH M7 does set thresholds.
13 In fact, that's how the acceptable
14 intakes for NDMA and NDEA were created by
15 the FDA.
16 MR. REEFER: John, you
17 interrupted -- John, you
18 interrupted his answer. I'd like
19 to --
20 MR. DAVIS: My apologies.
21 MR. REEFER: -- give him a
22 chance to finish.
23 THE WITNESS: I'm talking
24 about the ICH quality guidelines.

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1 I will give you that the ICH
2 Q3C and Q3D do set standards for
3 the amount of residual solvent and
4 the amount of inorganic impurities
5 or elemental impurities.
6 But beyond that, they do not
7 set standards for what the assay
8 has to be, what the level of
9 impurities have to be. There are
10 impurity guidelines that talk
11 about various categories, but they
12 don't say that the acceptance
13 criteria for a given impurity in a
14 given drug substance or drug
15 product has to meet a certain
16 level.
17 That's what I'm saying. And
18 that's the guidelines and
19 guidances that I was talking
20 about. Where it talks here about,
21 meet compendial or other
22 standards, to me, that's the
23 specification that's on file
24 with -- in their application at

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1 FDA.
2 BY MR. DAVIS:
3 Q. We saw that ICH M7 sets
4 acceptance criteria, correct?
5 MR. REEFER: Object to form.
6 Misstates the document.
7 But go ahead, Doctor.
8 THE WITNESS: The little bit
9 of M7 that I know, it has
10 information in there about these
11 impurities. But I don't know that
12 they actually said acceptance
13 criteria. I'd have to go back and
14 study that guideline.
15 BY MR. DAVIS:
16 Q. Okay. You haven't studied
17 it for your report here?
18 A. Correct.
19 Q. Or for your conclusion in
20 Paragraph 99 of your report, have you?
21 A. Correct.
22 Q. And you haven't even studied
23 the FDA's Orange Book definition of
24 therapeutic equivalence here for

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1 Paragraph 99 of your report, have you?
2 A. I have not.
3 Q. Do you see Number 5 a little
4 bit further down?
5 A. Yes.
6 Q. And they are manufactured in
7 compliance with current good
8 manufacturing practice regulations.
9 Do you see that as a
10 requirement that the FDA has for a drug
11 product to be considered therapeutically
12 equivalent?
13 A. Yes.
14 MR. DAVIS: Just a little
15 recordkeeping. I'm going to mark
16 Tabs 20, 21 and 22 as Exhibits-15
17 through 17.
18 - - -
19 (Whereupon, Exhibit
20 Sheinin-15, No Bates, 12/31/21
21 ProPharma Group Invoice
22 #PPGUS000581, was marked for
23 identification.)
24 - - -

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1 (Whereupon, Exhibit
2 Sheinin-16, No Bates, 1/31/22
3 ProPharma Group Invoice
4 #PPGUS000820, was marked for
5 identification.)
6 - - -
7 (Whereupon, Exhibit
8 Sheinin-17, No Bates, 2/28/22
9 ProPharma Group Invoice
10 #PPGUS001080, was marked for
11 identification.)
12 - - -
13 MR. DAVIS: Do you have
14 those, Jason? Those are the
15 invoices.
16 MR. REEFER: Yeah, I was --
17 I was understanding it was just
18 housekeeping, I wasn't about to
19 pull them up. Do you want me to?
20 MR. DAVIS: Sure. I do want
21 him to see them and verify them
22 for me, so.
23 MR. REEFER: Sure. Sorry, I
24 just -- I thought you were just

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1 going to attach them and move on.
2 Remind me what you're looking at,
3 20 --
4 MR. DAVIS: 20 through 22,
5 which are now Exhibits-15 through
6 17.
7 MR. REEFER: Three one-page
8 documents, correct?
9 MR. DAVIS: That's right.
10 MR. REEFER: I'm marking the
11 one dated 12/31/21 as
12 Exhibit-20 --
13 MR. DAVIS: Okay.
14 MR. REEFER: -- is that
15 correct?
16 MR. DAVIS: Yes. And then
17 do the January one for 21.
18 THE WITNESS: 15, 16 and 17
19 he said -- oh --
20 MR. DAVIS: Yes.
21 THE WITNESS: 15, 16 and 17.
22 MR. DAVIS: Yes. Thank you,
23 Dr. Sheinin.
24 December would be

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1 Exhibit-15. January, 16 and
2 February, 17.
3 MR. REEFER: All right.
4 BY MR. DAVIS:
5 Q. Okay. Just a few brief
6 housekeeping questions on these,
7 Dr. Sheinin.
8 Did you prepare these
9 invoices or did somebody else prepare
10 them?
11 A. Somebody else. I report my
12 time on a timekeeping system, and I
13 can't -- there have been -- let me back
14 up.
15 I used to file a time report
16 with NDA Partners, and then they went to
17 a timekeeping system, and I was using
18 that. And then they went to a different
19 timekeeping system.
20 So I don't know at what
21 point in time that this new timekeeping
22 system went into effect. But I think
23 it's -- since it's talking -- all these
24 are ProPharma Group, I believe it's the

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1 current system.
2 And I enter my time on a
3 daily basis if I'm doing any work for NDA
4 Partners. And I then enter the, in a
5 comment field, what work I did that day,
6 and it goes on a weekly basis.
7 Q. Okay. So even if you didn't
8 generate the actual invoice, the
9 description notations and dates,
10 quantities, et cetera, that's stuff you
11 would have written in your own words,
12 correct?
13 A. Correct.
14 Q. Okay. Are there any
15 invoices prior to -- if you look at
16 Exhibit-15, which is the December
17 invoice, did you do any work on this case
18 prior to December 13th or would that have
19 been the first time you encountered work
20 on this case?
21 A. I believe that's the first
22 time.
23 Q. Okay. And then the last --
24 Exhibit-17, the last entry is February

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1 17th, 2022.
2 Do you see that?
3 A. Yes.
4 Q. Could you estimate for me
5 the amount of time you've billed in this
6 case since February 17?
7 A. Not counting today?
8 Q. Sure. Not counting today.
9 A. I think it's somewhere in
10 the neighborhood of 15 to 17 hours this
11 month. But I can't say for certainty.
12 Q. Okay. Would all of that
13 time have been part of preparing for your
14 deposition today?
15 A. I believe so.
16 Q. Can you recall doing any
17 work after February 17 that was not
18 dedicated to preparing for today?
19 A. No, I -- I mean, I -- this
20 is when -- I reviewed the certificates of
21 analysis and I looked at some additional
22 FDA statements. But it was all in
23 relation to getting ready for today.
24 Q. Okay. Would that be the

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1 supplement to Exhibit B to your report,
2 where you say you reviewed the deposition
3 of Ron Najafi?
4 A. Yes.
5 MR. DAVIS: Let me --
6 just another housekeeping matter.
7 Let me introduce that into
8 evidence.
9 - - -
10 (Whereupon, Exhibit
11 Sheinin-18, No Bates, Supplement
12 to Exhibit B to the Report of Eric
13 Sheinin, Ph.D., was marked for
14 identification.)
15 - - -
16 BY MR. DAVIS:
17 Q. Okay. I've marked that as
18 Sheinin-18. And I don't need --
19 actually, here, what I'll do is just
20 screen share it.
21 Can you see that on your
22 screen, Dr. Sheinin?
23 A. Yes.
24 Q. It's a supplement to

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1 Exhibit B, the report of Eric Sheinin,
2 Ph.D., Deposition of Ron Najafi.
3 A. I see that.
4 Q. Was there anything else you
5 reviewed since submitting your expert
6 report on January 12th that didn't make
7 it into this supplemental exhibit,
8 supplement to Exhibit B?
9 A. I don't believe so.
10 Q. Okay.
11 MR. DAVIS: Okay. That's
12 all the questions I have for you
13 today, Dr. Sheinin. Thank you for
14 your time.
15 I'll pass the witness.
16 THE WITNESS: Thank you.
17 MR. REEFER: Does anyone
18 have questions on the phone or
19 remote?
20 Hearing none, John, let
21 me -- let's go off the record.
22 VIDEO TECHNICIAN: We're
23 going off the record. The time is
24 4:15 p.m.

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1 - - -
2 (Whereupon, a brief recess
3 was taken.)
4 - - -
5 VIDEO TECHNICIAN: We're
6 back on the record. The time is
7 4:51 p.m.
8 MR. DAVIS: For the record,
9 before you start your questions,
10 Jason. I'll note that we've been
11 on a break for over 30 minutes
12 since I concluded my questioning.
13 We'll reserve all rights
14 regarding how this is all going to
15 be allocated in terms of cost. So
16 I'm going to reserve all that on
17 the record.
18 You can go ahead, Jason.
19 MR. REEFER: I can also
20 respond. John, what's the basis
21 for your suggestion that my
22 taking -- I don't know if it was
23 30 minutes or not, but what's the
24 basis for your suggestion that I

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1 owe you costs for a 30-minute
2 break in a deposition?
3 MR. DAVIS: If we get a bill
4 for Dr. Sheinin's deposition time,
5 there will be a dispute over this
6 time period.
7 MR. REEFER: Okay. Well, I
8 guess you can raise that dispute
9 when you get the bill.
10 MR. DAVIS: Okay.
11 MR. REEFER: I don't -- I
12 don't understand the basis of your
13 objection. But let's just move
14 on, okay?
15 MR. DAVIS: Okay. Go ahead.
16 MR. REEFER: Thank you.
17 - - -
18 EXAMINATION
19 - - -
20 BY MR. REEFER:
21 Q. Dr. Sheinin, I just have a
22 few questions to clarify some of the
23 testimony that you've offered thus far
24 today. I'll be as brief as I can,

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1 recognizing it's already been a long day.
2 Do you remember,
3 Dr. Sheinin, this morning Mr. Davis asked
4 you a few questions about some of the
5 prior litigation work you've done as an
6 expert witness?
7 A. Yes, I remember.
8 Q. Okay. And one of the
9 questions Mr. Davis asked you was whether
10 your prior work as an expert witness was
11 all performed on behalf of pharmaceutical
12 manufacturers.
13 Do you recall that question?
14 A. I don't recall it in that
15 exact way.
16 Q. Do you recall that during
17 Mr. Davis's previous questions to you, he
18 asked whether, during your prior work as
19 an expert consultant, that work was
20 performed on behalf of pharmaceutical
21 manufacturers?
22 A. It was.
23 Q. And just to be clear, that
24 prior work as an expert consultant

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1 involved litigation featuring
2 pharmaceutical manufacturers as both
3 plaintiffs and defendants, correct?
4 A. Yes.
5 Q. Were the only --
6 MR. DAVIS: Objection.
7 Leading.
8 BY MR. REEFER:
9 Q. Were the only parties to
10 those lawsuits pharmaceutical
11 manufacturers?
12 A. Yes.
13 Q. So, therefore, if you were
14 going to be involved as an expert
15 consultant, would you have any choice but
16 to represent a pharmaceutical
17 manufacturer?
18 MR. DAVIS: Object to form.
19 THE WITNESS: I doubt that
20 anybody would hire me.
21 BY MR. REEFER:
22 Q. And to the best of your
23 recollection, did you represent
24 pharmaceutical manufacturers that were

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1 both plaintiffs and defendants?
2 A. I believe so.
3 Q. Dr. Sheinin, I think marked
4 as Exhibit-3 was a warning letter issued
5 to Unit 8, dated November 5th, 2019.
6 Do you recall talking about
7 that with Mr. Davis?
8 A. Yes.
9 Q. Does a warning letter
10 constitute final agency action by the
11 FDA?
12 A. No, it doesn't.
13 Q. Have you reviewed FDA's
14 website to determine whether Mylan, at
15 any point in time, has been placed on an
16 import alert?
17 A. I have. I could not find
18 any -- any time that Mylan had an import
19 alert. I don't know how far back the
20 database goes, but it came back and said
21 no -- no response or something to that
22 effect.
23 Q. So based on your review of
24 information published by FDA, you've seen

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1 no evidence to suggest Mylan was placed
2 on import alert following the recall of
3 valsartan, correct?
4 A. Correct.
5 Q. Under the FDCA, can FDA
6 permit the sale of drug product known by
7 the agency to be adulterated or
8 misbranded?
9 A. I don't believe so. I would
10 think not.
11 Q. If you assume that Mylan's
12 Unit 8 continued to manufacture drug
13 substance for the United States market
14 from the time of the recalls to present,
15 would that confirm in your mind that FDA
16 did not consider drug substance from
17 Unit 8 to be misbranded or adulterated?
18 A. Yes.
19 MR. DAVIS: Wait. Objection
20 to form. Objection. Leading.
21 BY MR. REEFER:
22 Q. Do you remember,
23 Dr. Sheinin, having a discussion with
24 Mr. Davis about the M7 guidance?

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1 A. Yes.
2 Q. Did you testify that the M7
3 guidance was not one which you regularly
4 worked with during your time at FDA?
5 A. I don't believe I worked
6 with it at all at FDA.
7 MR. REEFER: And for the
8 record, I think the M7 guidance
9 was marked as Exhibit-5, but I
10 don't want to mess that up.
11 BY MR. REEFER:
12 Q. If you'd pull out Exhibit-5,
13 please, Dr. Sheinin.
14 A. Okay.
15 Q. Dr. Sheinin, do you recall a
16 portion of your testimony with Mr. Davis
17 where he asked you to read beginning on
18 Page 5 of Exhibit-5 under the heading,
19 General Principles?
20 A. Yes, I remember. In fact, I
21 had to read this -- parts of two pages,
22 right?
23 Q. Correct. Yes, sir.
24 Dr. Sheinin, if you look at

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1 the second paragraph under general
2 principles, you'll see a sentence
3 beginning with, A threshold of
4 toxicological concern.
5 Do you see that paragraph,
6 sir?
7 A. Yes.
8 Q. And in the second sentence,
9 does this document state that, The
10 methods upon which the TTC -- that being
11 the threshold of toxicological concern --
12 is based are generally considered to be
13 very conservative since they involve a
14 simple linear extrapolation from the
15 dose, giving a 50 percent tumor incidence
16 to a 1 in 106 incidence, using TD50 data
17 for the most sensitive species and most
18 sensitive site of tumor induction?
19 Do you see that language,
20 sir?
21 MR. DAVIS: Before you
22 answer, Dr. Sheinin, let me place
23 an objection on the record here.
24 He's testified a billion

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1 times today he's not a
2 toxicologist, so asking him about
3 the substance of how thresholds
4 for toxicological concern are
5 created is totally outside of --
6 not only of his report but also of
7 his expertise, as he's admitted
8 today.
9 And I'll object to form,
10 just for the heck of it.
11 MR. REEFER: I understand
12 your position to be that the
13 section of M7 that you required my
14 witness to read cannot now be read
15 into the record; is that your
16 position, counsel?
17 MR. DAVIS: No, I'm
18 objecting to where this is going,
19 which is -- which is --
20 MR. REEFER: You don't
21 know -- John -- you have no idea
22 where this is going, John.
23 MR. DAVIS: I have a pretty
24 good idea. All right, go ahead

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1 and answer the question.
2 Object to form.
3 BY MR. REEFER:
4 Q. Yes.
5 The question was, do you see
6 that language; yes or no?
7 A. Yes.
8 Q. If you turn the page,
9 Dr. Sheinin, to Page 6 of the M7 guidance
10 marked as Exhibit-5, you'll see some
11 language, a sentence beginning with the
12 words, The use of a numerical cancer risk
13 value.
14 Do you see that, sir?
15 A. Yes.
16 Q. And does the M7 guidance
17 say, The use of a numerical cancer risk
18 value (1 in 100,000) and its translation
19 into risk-based doses (TTC) is a highly
20 hypothetical concept that should not be
21 regarded as a realistic indication of the
22 actual risk.
23 Did I read that correctly,
24 sir?

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1 MR. DAVIS: Object to form.
2 MR. REEFER: What's the
3 nature of the objection, counsel?
4 MR. DAVIS: I said object to
5 form.
6 You can go ahead.
7 MR. REEFER: Right. I just
8 wanted to clarify the nature so I
9 can fix it.
10 MR. DAVIS: Well, it's the
11 inherent nature of asking this
12 witness about concepts that he's
13 not an expert in. You're asking
14 him to read a sentence that he
15 doesn't understand.
16 MR. REEFER: Did you ask him
17 to do the same thing, counsel?
18 MR. DAVIS: No, I didn't. I
19 asked him -- I had him clarify
20 that he's never seen this
21 document, didn't look at it,
22 didn't consider it.
23 MR. REEFER: And did you ask
24 him to read it, counsel?

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1 MR. DAVIS: Sure. Yeah, I
2 asked him to read it to -- in
3 order to -- in order to get the
4 testimony that he never looked at
5 it and never considered it.
6 MR. REEFER: Okay. Thank
7 you.
8 BY MR. REEFER:
9 Q. Let me continue,
10 Dr. Sheinin.
11 The next sentence reads,
12 Nevertheless, the TTC concept provides an
13 estimate of the safe exposures for any
14 mutagenic compound. However, exceeding
15 the TTC is not necessarily associated
16 with an increased cancer risk, given the
17 conservative assumptions employed in the
18 derivation of the TTC value.
19 Do you see those sentences,
20 Doctor?
21 A. Yes.
22 MR. DAVIS: Objection.
23 BY MR. REEFER:
24 Q. The exact sentence reads --

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1 MR. REEFER: I haven't
2 finished my -- I haven't finished
3 stating my question.
4 BY MR. REEFER:
5 Q. The next sentence reads, The
6 most likely increase in cancer incidence
7 is actually much less than 1 in 100,000.
8 Did I read that correctly?
9 A. Yes.
10 Q. The next sentence reads, In
11 addition, in cases where a mutagenic
12 compound is a noncarcinogen in a rodent
13 bio assay, there would be no predicted
14 increase in cancer risk.
15 Did I read that correctly?
16 MR. DAVIS: Jason, are you
17 just going to ask him to confirm
18 that you're reading sentences in
19 the document? Or are you going to
20 actually ask him any questions
21 about this stuff that he doesn't
22 understand?
23 MR. REEFER: I am --
24 MR. DAVIS: This is an utter

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1 waste of time. This is an
2 absolute waste of time, if this is
3 what you're doing.
4 MR. REEFER: Counsel, I am
5 putting on the record what you
6 asked my witness to read so as to
7 allow you to ask him questions.
8 MR. DAVIS: I didn't ask him
9 anything about derivation of TTCs
10 or how they were derived for
11 nitrosamines, because he doesn't
12 know anything about that. He's
13 not a toxicologist.
14 This is -- this is an
15 absolute waste of time. You all
16 have other experts -- had other
17 experts who have opined on this
18 stuff, some of whom have been
19 struck.
20 But you all had plenty of
21 experts that could -- they can
22 talk about this. This is not one
23 of those experts, as he himself
24 has testified.

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1 This is a waste of time.
2 I'm going to make that a
3 continuing objection. Keep going,
4 if you like.
5 MR. REEFER: Thank you.
6 BY MR. REEFER:
7 Q. The next sentence,
8 Dr. Sheinin, I believe, reads, Based on
9 all of the above considerations, any
10 exposure to an impurity that is later
11 identified as a mutagen is not
12 necessarily associated with an increased
13 cancer risk for patients already exposed
14 to the impurity.
15 Did I read that correctly?
16 A. Yes, you did.
17 Q. Is it true that a new drug
18 application or abbreviated new drug
19 application may contain standards and
20 specifications in addition to what's
21 found in a compendial monograph?
22 A. Yes.
23 Q. Do you remember counsel
24 asking you questions with respect to

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1 Exhibit-6, the valsartan drug substance
2 monograph?
3 A. Yes.
4 Q. If you look -- if you focus
5 simply on the monograph, irrespective of
6 any other standards or specifications
7 that might be in place, is it true that
8 so long as nitrosamine impurities were
9 not detected above 0.1 percent, the drug
10 substance would comply with compendial
11 standards?
12 A. It would.
13 Q. To this day, to the best of
14 your knowledge, does FDA permit the sale
15 of drug products within the United States
16 containing NDMA or NDEA, so long as those
17 levels are below acceptable intake
18 limits?
19 A. I believe that's true.
20 MR. DAVIS: Object to form.
21 BY MR. REEFER:
22 Q. Dr. Sheinin, you were asked
23 a series of questions related to, I
24 think, three or four consecutive

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1 exhibits, including an e-mail exchange,
2 DMF information requests, and a process
3 validation report.
4 Do you remember generally
5 that line of questioning from Mr. Davis?
6 A. Oh. Yeah, I remember.
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
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18 [REDACTED]

19 [REDACTED]

20 [REDACTED]

21 [REDACTED]

22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

Page 276

1 [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 Q. You had discussed,

5 Dr. Sheinin, concepts about whether the

6 impurity profile between a generic drug

7 and an innovator or reference-listed drug

8 must be identical.

9 Do you remember that

10 discussion?

11 A. Yes.

12 Q. Do you understand that

13 oftentimes what's referred to as a

14 reference-listed drug is an NDA holder or

15 what some people refer to as an innovator

16 drug?

17 A. Quite often it is. It's not

18 necessarily, but not -- most of the time,

19 yeah. It's pretty -- pretty common.

20 Q. For -- and I'll refer to,

21 you know, an NDA holder as an innovator

22 drug; is that okay, for shorthand?

23 A. Yes, okay.

24 Q. In your experience at FDA,

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1 will you see batch-by-batch variants in

2 the impurity profiles of API used to

3 manufacture innovator drugs?

4 A. Yeah. I think I mentioned

5 that during testimony today, that there's

6 going to be variation from batch to batch

7 and even sometimes there's -- a given

8 impurity is not present at the time of

9 manufacture and sometimes it is,

10 especially if it's a very low-level

11 impurity.

12 Q. Dr. Sheinin, in your

13 experience at FDA, are you aware of

14 instances where the manufacturer of an

15 innovator drug sources API from multiple

16 sources?

17 A. Yes. Sometimes they do that

18 in their original NDA, sometimes they do

19 it, through a supplement, to add another

20 manufacturer. And I have seen NDAs where

21 there were more than two manufacturers,

22 especially for a, quote/unquote,

23 blockbuster drug, where there's times

24 that one -- one source of a drug

<p>Page 278</p> <p>1 substance is having issues and companies 2 need to have alternate sources. 3 Q. When a manufacturer of an 4 innovator drug sources API from multiple 5 sources, do those API manufacturers have 6 to use identical processes? 7 A. They don't have to. 8 Sometimes the innovator may have the 9 patent on the synthetic scheme and they 10 want their suppliers to use the same 11 scheme. Sometimes that's not the case 12 and whoever they are purchasing the drug 13 substance from is using different routes 14 of synthesis. 15 Q. When an innovator drug 16 manufacturer sources API from multiple 17 manufacturers and those API manufacturers 18 utilize separate and distinct 19 manufacturing processes, would you expect 20 there to be differences in the impurity 21 profile of the API? 22 A. Definitely, I would. 23 Q. Does the FDCA adopt the USP 24 compendial standard as the standard by</p> <p>Page 279</p> <p>1 which products are evaluated for 2 adulteration? 3 A. Yes. I think that's in my 4 report. 5 Q. If a product complies with 6 the compendial monograph, does that mean 7 it's not adulterated? 8 MR. DAVIS: Objection. 9 Calls for a legal conclusion that 10 he was unwilling to provide to me 11 in his direct testimony here. 12 BY MR. REEFER: 13 Q. Do you offer the opinion 14 that the standards set forth in Mylan's 15 DMF were consistent with the valsartan 16 USP monograph for a drug substance? 17 A. Yes. The fact that 18 valsartan -- Mylan's valsartan is on the 19 market and being sold in the U.S., to me, 20 that says the quality of the valsartan 21 API is in conformance with the USP 22 monograph. 23 Q. And you did not need to 24 review the drug master file for that</p>	<p>Page 280</p> <p>1 opinion, did you? 2 A. No, I did not. I also 3 looked at, I think I had mentioned 4 earlier, two certificates of analysis. 5 And I compared the test in the 6 certificates of analysis with the USP 7 monograph and found them to be in 8 agreement. 9 Q. Did -- have you had an 10 opportunity to review the label from 11 Mylan's valsartan drug product? 12 A. I have. And I -- I looked 13 at the package insert. And in Section 14 11, where it talks about the description, 15 I could see that the heading there was 16 valsartan tablets USP. And in the 17 discussion of the active ingredient, it 18 says valsartan USP. 19 Q. And does that -- why is that 20 significant to you? 21 A. Because that means the -- 22 both the drug product and the drug 23 substance meet the requirements set forth 24 in the compendial monographs for those</p> <p>Page 281</p> <p>1 two items. 2 Q. Does the potential presence 3 of NDEA, at levels up to 1.57 parts per 4 million, change your opinion that drug 5 substance manufactured in accordance with 6 the specifications set forth in Mylan's 7 DMF would be compliant with compendial 8 standards? 9 A. There's not -- 10 MR. DAVIS: Object to form. 11 BY MR. REEFER: 12 Q. Okay. Can you explain why 13 that is? 14 COURT REPORTER: I'm sorry. 15 I need that answer repeated. 16 MR. REEFER: Could you 17 repeat your answer, Dr. Sheinin. 18 THE WITNESS: I think I 19 said, no, it does not. 20 BY MR. REEFER: 21 Q. And can you explain why it 22 does not? 23 A. Because at 1.57 PPM, it 24 would still meet the acceptance criteria</p>
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1 in the test for any other impurity of 0.1
2 percent.
3 Q. Do you remember a portion of
4 your report where you discuss whether
5 routine testing performed on drug
6 substance would have allowed for the
7 detection of trace levels of nitrosamine
8 impurities?
9 A. I do recall.
10 Q. Is it your opinion that
11 routine testing would not have detected
12 levels of NDEA as found in some batches
13 of Mylan's drug substance?
14 MR. DAVIS: Objection.
15 Object to form.
16 THE WITNESS: Yes.
17 MR. DAVIS: Objection.
18 Vague as to what "routine testing"
19 means.
20 MR. REEFER: Was your answer
21 yes?
22 THE WITNESS: The answer is
23 yes.
24 BY MR. REEFER:

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1 Q. And what's the basis of that
2 opinion?
3 A. The basis of my opinion is
4 the 30 years I had at the FDA, both in
5 the laboratory and as a supervisory
6 review chemist, and my experience at USP.
7 And even before I worked at
8 USP, I actually served as a volunteer on
9 a number of USP expert committees,
10 evaluating proposed monographs for -- to
11 go into the book.
12 And just from my experience,
13 routine testing would not have picked up
14 an impurity at that low of a level.
15 The fact that FDA had to
16 resort to using mass spec -- using mass
17 spec is a very sensitive detector to
18 begin with, and they had to make that
19 detector even more sensitive because they
20 were looking at a single ion.
21 When you introduce a
22 chemical into a mass spectrometer, it's
23 ionized and then it breaks down into
24 fragments. The initial ion is called the

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1 parent ion, and as it breaks down it
2 forms daughter ions.
3 And that -- to be able to
4 look at a single ion for NDEA or a single
5 ion for NDMA increases the sensitivity of
6 that method. So it's -- basically, I
7 guess I would say it's -- compared to a
8 routine GC or LC analysis, I would call
9 it supercharged. It's many -- it's
10 multiple times more sensitive than a
11 routine procedure.
12 MR. DAVIS: I can't hear
13 you, Jason.
14 VIDEO TECHNICIAN: The phone
15 is on mute, I think.
16 The phone disconnected.
17 - - -
18 (Whereupon, a discussion off
19 the record occurred.)
20 - - -
21 MR. DAVIS: Let's go off the
22 record.
23 VIDEO TECHNICIAN: Going off
24 the record. The time is 5:23 p.m.

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1 - - -
2 (Whereupon, a brief recess
3 was taken.)
4 - - -
5 VIDEO TECHNICIAN: We are
6 back on the record. The time is
7 5:29 p.m.
8 BY MR. REEFER:
9 Q. Dr. Sheinin, I understand
10 that we were just disconnected from the
11 phone line used for this Zoom deposition
12 and that madam court reporter read back
13 your prior answer.
14 Did you hear her recite that
15 answer?
16 A. I did.
17 Q. Was there any additional
18 information that you sought to provide in
19 response to my previous question?
20 A. No.
21 Q. Has --
22 MR. DAVIS: Are you
23 speaking, Jason, or did we lose
24 you again?

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1 MR. REEFER: No, you haven't
 2 lost me yet, John. I was -- my
 3 wheels don't turn as fast as yours
 4 do, John, as you can probably
 5 tell.
 6 BY MR. REEFER:
 7 Q. Dr. Sheinin, has -- has FDA
 8 made statements indicating that the
 9 properties of nitrosamine impurities make
 10 them hard to detect in standard
 11 laboratory testing?
 12 A. They have.
 13 MR. DAVIS: Object to form.
 14 Object to the extent that it's not
 15 listed in his -- in the four
 16 corners of his report or reliance
 17 materials, whatever this is
 18 calling for, these statements.
 19 BY MR. REEFER:
 20 Q. With respect to your -- the
 21 opinion you offered regarding the
 22 capabilities of routine testing to detect
 23 levels of NDEA as found in some batches
 24 of Mylan's drug substance, is it relevant

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1 for you to compare the specification set
 2 forth in the compendium of not more than
 3 0.1 percent versus the levels of NDEA
 4 detected in Mylan's drug?
 5 A. Yes.
 6 Q. How so?
 7 A. The levels that are found in
 8 Mylan's API would be well below the .1
 9 percent. So the testing of the
 10 impurity -- testing for impurities in the
 11 API, it would pass if -- unless -- unless
 12 there was another impurity of some
 13 unknown that was greater than .1 percent.
 14 Q. And --
 15 A. The NDEA or NDMA, if it was
 16 present, would be well below .1 percent.
 17 Q. And just, I guess, for
 18 purposes of comparing apples to apples,
 19 does .1 percent translate to 1,000 parts
 20 per million?
 21 A. Yes.
 22 Q. And when I refer to routine
 23 testing, did you understand that to mean
 24 the high-performance liquid

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1 chromatography methods set forth and
 2 described in the monograph for valsartan?
 3 A. Yes.
 4 MR. REEFER: I don't have
 5 any further questions at this
 6 time, though I may, depending on
 7 whether or not Mr. Davis does.
 8 MR. DAVIS: Okay. Just a
 9 few follow-ups, Dr. Sheinin. And
 10 I'll try to take them in the order
 11 in which they appeared.
 12 - - -
 13 EXAMINATION
 14 - - -
 15 BY MR. DAVIS:
 16 Q. You testified to me earlier
 17 that you weren't an expert and not
 18 qualified to offer opinions on risk
 19 assessment; is that right?
 20 A. Yeah. I'm not.
 21 Q. So you wouldn't know how an
 22 in-process parameter could become what
 23 the FDA refers to as a critical quality
 24 attribute or a critical process

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1 parameter; is that right?
 2 A. I -- I have an understanding
 3 of what critical quality parameters are.
 4 They are parameters that are critical to
 5 the manufacturing process. And --
 6 Q. And the determination of
 7 their -- sorry, go ahead.
 8 A. Go ahead.
 9 Q. The determination of whether
 10 they are critical or not is through a
 11 risk assessment pursuant to ICH Q9,
 12 correct?
 13 A. I believe it's in Q9.
 14 Q. Okay. And do you have any
 15 idea of what the FDA expects in terms of
 16 inclusion in a DMF regarding critical
 17 quality attributes or critical process
 18 parameters?
 19 A. I believe FDA expects them
 20 to be included in the description of the
 21 manufacturing process and the development
 22 report and so on.
 23 Q. Okay. Thank you.
 24 Counsel asked you some

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1 questions regarding routine testing.
2 Do you recall that? And
3 whether GC-MS did something that would be
4 considered routine testing or not?
5 MR. REEFER: Object to the
6 form. Beyond the scope of my
7 direct.
8 THE WITNESS: I recall he
9 asked me questions about routine
10 testing, and I would not consider
11 GC-mass spec to be routine
12 testing.
13 BY MR. DAVIS:
14 Q. When you say "routine
15 testing," are you referring to routine
16 testing that's done as part of, like, a
17 USP monograph, like the specification and
18 testing procedure for a USP monograph or
19 an approved DMF specification or ANDA
20 spec?
21 A. Or NDA spec. All of that.
22 Q. Right. But an
23 already-approved specification, correct?
24 A. No. A company that's

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1 submitting an ANDA or an NDA today, for
2 the most part, will be using routine
3 analytical procedures.
4 GC-mass spec is not anything
5 that I would consider routine.
6 Q. Even though the FDA expects
7 it to be done when unknown impurities are
8 found?
9 A. I'm not aware that the FDA
10 said you have to use GC-mass spec anytime
11 there's an unknown impurity.
12 I'm aware that the method
13 that FDA published for valsartan
14 impurities -- nitrosamine impurities in
15 valsartan is a GC-mass spec method. But
16 I'm not aware that FDA has said that any
17 unknown has to be looked at by GC-mass
18 spec.
19 Q. You are aware that the DEA
20 requires manufacturers to evaluate
21 unknown impurities?
22 Are you aware of that?
23 MR. REEFER: Object to form.
24 Misstates the testimony.

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1 But go on.
2 THE WITNESS: According to
3 ICH Q3A and Q3B, companies are --
4 well, as I said earlier, FDA
5 considers ICH guidance as
6 recommendations. So, accordingly,
7 FDA is recommending that those two
8 guidances be followed in terms of
9 determine -- making a
10 determination of the impurities in
11 a given API or a drug product.
12 I don't see anywhere in
13 those guidances where ICH says you
14 have to use GC-mass spec.
15 BY MR. DAVIS:
16 Q. I'm talking about the FDA
17 requiring manufacturers to evaluate
18 unknown impurities.
19 Are you aware of that
20 obligation?
21 A. I'm not -- I'm not aware of
22 a specific guidance that says -- anything
23 beyond what's in Q3A or Q3B as to how
24 to -- not how to, but as to what the

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1 criteria would be for reporting and
2 identifying those impurities.
3 MR. DAVIS: I'm marking Tab
4 16 as Exhibit-19.
5 - - -
6 (Whereupon, Exhibit
7 Sheinin-19, No Bates, Warning
8 Letter, Mylan Laboratories
9 Limited -- Unit 7, was marked for
10 identification.)
11 - - -
12 MR. REEFER: I'll take a --
13 will you give me a standing
14 objection, John, to the use of
15 this exhibit on the basis that
16 it's beyond the scope of my direct
17 and, also, it does not apply to
18 any facility that's been deemed to
19 be at issue in this litigation?
20 MR. DAVIS: Standing
21 objection granted, but also
22 disagreed with.
23 MR. REEFER: Very lawyerly.
24 BY MR. DAVIS:

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1 Q. You told me earlier,
2 Dr. Sheinin, you hadn't looked at
3 anything related to Unit 7; is that
4 right?
5 A. That's right.
6 Q. Okay. Do you recognize this
7 as a warning letter that was issued to
8 Unit 7 in August of 2020?
9 MR. REEFER: Objection.
10 Beyond the scope.
11 THE WITNESS: Yes.
12 BY MR. DAVIS:
13 [REDACTED]

Page 295

1 [REDACTED]

Page 296

1 [REDACTED]

Page 297

1 [REDACTED]

16 BY MR. DAVIS:
17 Q. You wouldn't think it
18 relevant to know what the FDA has been
19 advising manufacturers their obligations
20 are regarding analytical testing --
21 MR. REEFER: Object to form.
22 BY MR. DAVIS:
23 Q. -- specifically as it
24 relates to nitrosamines?

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1 MR. REEFER: Object to form.
2 Misstates the document. Beyond
3 the scope. Foundation.
4 Go ahead.
5 THE WITNESS: I have no idea
6 whatsoever what FDA has asked any
7 other defendant in this case. I
8 have no way of knowing that.
9 It's -- I mean, you know it.
10 But I have no way to know that.
11 How would you think I would know
12 that?
13 BY MR. DAVIS:
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

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1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 So I don't require a
9 response to that question, but -- or
10 statement, rather.
11 MR. REEFER: Object to the
12 colloquy.
13 BY MR. DAVIS:
14 Q. But let me ask you this,
15 Dr. Sheinin.
16 Is one of the ways to
17 thoroughly evaluate an unknown peak in a
18 GC FID by doing GC-MS?
19 MR. REEFER: Object to form.
20 Beyond the scope. Beyond the
21 direct.
22 Go ahead, Dr. Sheinin, if
23 you know.
24 THE WITNESS: It's one

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1 possible way.
2 BY MR. DAVIS:
3 Q. Okay. Would it be the most
4 prevalent possible way in terms of
5 evaluating unknown peaks that appear in a
6 GC FID?
7 MR. REEFER: Same objection.
8 THE WITNESS: It would be a
9 very good way. I guess partly it
10 depends on if -- if the
11 material -- well, it's one way --
12 GC-mass spec would be one way to
13 evaluate a peak coming out of a GC
14 that's an unknown by
15 flame-ionization detection.
16 But we've been talking here
17 about solvents and recovered
18 solvents. When you mentioned the
19 API, my question is, are you
20 talking about, when you talk about
21 an API, the assay? Are you
22 talking about the impurity test
23 that's in the specification or in
24 the USP monograph? Or are you

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1 talking about a solvent?
2 There's -- there's a world
3 of differences in how you go about
4 testing for unknowns in the API
5 versus these nitrosamines. So
6 there's -- I just feel that you
7 were not specific enough in what
8 you were asking me.
9 BY MR. DAVIS:
10 Q. Okay. Well, I think you've
11 answered my question, which is, GC-MS is
12 a prevalent way to thoroughly evaluate an
13 unknown peak in a GC, correct?
14 A. My premise was that I do not
15 consider GC-mass spec to be a routine
16 procedure. And I stand by that. I do
17 not consider it to be routine.
18 Q. You don't consider it to be
19 routine in -- as a procedure that's in an
20 approved specification, that's right.
21 Is that what your testimony
22 is?
23 A. Yes.
24 Q. Okay.

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1 A. It may -- it may be in an
2 approved specification today because of
3 nitrosamines. But I do not consider it
4 to be routine.
5 Q. In an approved
6 specification?
7 A. In an approved specification
8 or in an application for marketing
9 approval.
10 Q. You don't think that it's
11 routine that all the workup in a DMF that
12 goes into an ANDA application or drug
13 master file for a product that's to be
14 approved, you don't think that it's
15 routine that companies -- manufacturers
16 do GC-MS?
17 MR. REEFER: Objection.
18 Asked and answered.
19 THE WITNESS: I do not
20 consider it to be a routine
21 quality control test.
22 BY MR. DAVIS:
23 Q. Okay. A routine quality
24 control test. Okay.

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1 A. Well, you're talking about
2 quality control of a product. It's not
3 a -- it's not a routine test.
4 Q. Right. But quality control
5 is analytical chemistry for an approved
6 product, right?
7 A. Or it's a proposed
8 specification for inclusion in an
9 application of an ANDA or NDA. It's the
10 same thing. It's still -- it's a quality
11 control test.
12 Q. Are you aware that --
13 A. That we're talking about.
14 Q. Are you aware that Mylan's
15 own toxicologist testified to me that he
16 gets about, like, 3 to 4,000 requests for
17 GC-MS per year?
18 Did you review Lance Monar's
19 testimony? It wasn't even provided to
20 you, was it?
21 MR. REEFER: Object to form.
22 Foundation. Beyond the scope.
23 THE WITNESS: I'd have to
24 look on the list in Appendix B.

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1 But as I said earlier, I have not
2 reviewed any of those testimonies
3 from anybody from Mylan.
4 BY MR. DAVIS:
5 Q. Okay. And that would
6 include, also, Derek Glover's testimony;
7 you haven't reviewed any of his, even
8 though it is listed on Exhibit B, right?
9 MR. REEFER: Objection.
10 Literally just answered.
11 But go ahead, Dr. Sheinin.
12 THE WITNESS: I have not
13 reviewed any testimony from
14 anybody at Mylan.
15 BY MR. DAVIS:
16 [REDACTED]

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1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 BY MR. DAVIS:
17 Q. Okay. Thank you.
18 You told Mr. Reefer that
19 even a -- a Mylan valsartan product that
20 had 1.57 parts per million NDEA would
21 still meet compendial standards because
22 unknown impurities are controlled in the
23 USP monograph at not more than .1
24 percent, which is 1,000 parts per

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1 million, right?

2 A. I believe I qualified that

3 also by saying in the specification in

4 the approved application as well.

5 Q. So why did the recalls even

6 happen, then, if that's what -- if NDEA

7 was only to be controlled at not less

8 than 1,000 parts per million, which

9 appears to be your expert opinion, why

10 are we here? Why did these recalls

11 happen?

12 A. I did not -- I did not say

13 that -- I forget what your question was

14 already. It's been a long day.

15 Can you repeat your

16 question?

17 Q. Sure. And I appreciate it's

18 been a long day.

19 You testified to Mr. Reefer,

20 in response to one of his questions, that

21 a Mylan valsartan product containing 1.57

22 parts per million NDEA would still meet

23 compendial -- the USP monograph for

24 valsartan which controlled any other

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1 impurities at .1 percent; is that right?

2 A. Yes.

3 Q. So if that's the case, why

4 did the recalls happen? Can you tell me

5 that?

6 MR. REEFER: Object to form.

7 Beyond the scope. Beyond the

8 redirect.

9 THE WITNESS: The recalls

10 happened because FDA was told that

11 there were nitrosamines in some

12 products, and FDA's investigation

13 showed that there was -- there was

14 a theoretical risk and,

15 ultimately, they determined that

16 there needs to be a lower

17 acceptance criteria for

18 nitrosamines. And they called it

19 the acceptable intake level.

20 And there had to be a

21 development of more sensitive

22 analytical procedures to be able

23 to detect and quantify those

24 nitrosamines.

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1 So that's why there was a

2 recall, and I -- I would expect

3 that companies manufacturing these

4 products will have to include

5 testing for nitrosamines in their

6 specification as a -- doing a

7 supplement to their approved

8 application.

9 So there would be an

10 additional test beyond what's in

11 the USP. And I would hope that

12 companies would submit the same

13 information to USP, for USP to be

14 able to update the monograph for

15 all of the sartans.

16 BY MR. DAVIS:

17 Q. So why does it even matter

18 that USP monograph had a not more than .1

19 percent limit, if that's not even the

20 limit that applied to nitrosamines at any

21 point?

22 MR. REEFER: Object to form.

23 Object to form. It misstates the

24 testimony.

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1 THE WITNESS: I don't -- I

2 just don't understand your

3 question. It's --

4 BY MR. DAVIS:

5 Q. Well, I don't understand

6 your report.

7 MR. REEFER: Come on.

8 MR. DAVIS: Let me ask it

9 again. Let me ask it again.

10 BY MR. DAVIS:

11 Q. Why would it be important

12 for you, in your report, that the USP

13 monograph had a not more than .1 percent

14 limit for other impurities if that's not

15 even the limit that applied to

16 nitrosamines at any point? Why is that

17 relevant to your report?

18 MR. REEFER: Objection to

19 form. Misstates the testimony.

20 But go ahead, Doctor.

21 THE WITNESS: I'm totally

22 confused by now.

23 The USP monograph is

24 recognized in the Food, Drug and

<p style="text-align: right;">Page 310</p> <p>1 Cosmetic Act as being an official 2 compendium. And that monograph 3 has to be met in order for a 4 product not to be considered 5 adulterated. 6 That's why the monograph is 7 important. And that's why the 8 acceptance criteria in the 9 specification for unknown 10 impurities is important. 11 BY MR. DAVIS: 12 Q. Have you looked at what 13 the -- what the definition of adulterated 14 is in the FD&C Act at all recently? 15 A. Yes, I have. I believe I 16 have it in my report. 17 Q. Okay. And so you'll agree 18 with me, then, that a product is 19 adulterated if it's manufactured in a way 20 where the manufacturer could not assure 21 that it would -- well, let me just read 22 you the language so I'm not confused or 23 misstating it. 24 MR. REEFER: What are you</p>	<p style="text-align: right;">Page 312</p> <p>1 quality and purity characteristics which 2 it purports or is represented to possess. 3 Have you seen that language 4 before? 5 A. Yes. 6 Q. Okay. So you agree with me, 7 then, that a drug is adulterated if it's 8 manufactured out of compliance with GMP, 9 correct? 10 MR. REEFER: Object to form. 11 Object to form. Beyond the scope. 12 THE WITNESS: The -- that 13 definition is -- I want to look at 14 the definition I copied into my 15 report. 16 MR. REEFER: He's quoting 17 from a different subsection. 18 THE WITNESS: Oh, okay. 19 Can you read that again? 20 MR. DAVIS: Sure. 21 BY MR. DAVIS: 22 Q. A drug or a device shall be 23 deemed to be adulterated -- and then this 24 is A1 -- or A2B, Subsection A2B, If it is</p>
<p style="text-align: right;">Page 311</p> <p>1 reading from, John? 2 MR. DAVIS: 21 USC 351. 3 BY MR. DAVIS: 4 Q. A drug or device shall be 5 deemed adulterated -- 6 A. Wait. Wait. 7 MR. REEFER: Hold on. He 8 said 21 USC 351. 9 THE WITNESS: Okay. I 10 thought you said USP. 11 MR. DAVIS: 21 USC 351, 12 United States Code. 13 BY MR. DAVIS: 14 Q. A drug or a device shall be 15 adulterated, if it is a drug, and the 16 methods used in, or the facilities or 17 controls used for, its manufacture, 18 processing, packing or holding do not 19 conform to or are not operated or 20 administered in conformity with current 21 good manufacturing practice to assure 22 that such drug meets the requirements of 23 this chapter as to safety and has the 24 identity and strength, and meets the</p>	<p style="text-align: right;">Page 313</p> <p>1 a drug and the methods used in, or the 2 facilities or controls used for, its 3 manufacture, processing, packing or 4 holding do not conform to or are not 5 operated or administered in conformity 6 with current good manufacturing practice 7 to assure that such drug meets the 8 requirements in this chapter as to safety 9 and has the identity and strength, and 10 meets the quality and purity 11 characteristics which it purports or is 12 represented to possess. 13 Do you agree with me that 14 that's -- that's a definition of an 15 adulterated drug, a situation in which a 16 drug becomes adulterated, per federal 17 law? 18 A. Yes. 19 Q. Okay. And, in fact, that's 20 what Mylan was told in its November 2019 21 Unit 8 warning letter, Exhibit-3, was it 22 not? 23 MR. REEFER: Objection. 24 BY MR. DAVIS:</p>

<p style="text-align: right;">Page 314</p> <p>1 Q. We saw that language, right?</p> <p>2 MR. REEFER: Object to form.</p> <p>3 You've covered this in cross. You</p> <p>4 know, asked and answered.</p> <p>5 But go ahead.</p> <p>6 THE WITNESS: And yet FDA,</p> <p>7 within a short period of time,</p> <p>8 allowed Mylan to reintroduce their</p> <p>9 valsartan. So there was no legal</p> <p>10 action taken, as far as I know,</p> <p>11 about the valsartan that was the</p> <p>12 subject of that inspection.</p> <p>13 BY MR. DAVIS:</p> <p>14 Q. Okay. And for about the</p> <p>15 umpteenth time today, you have no idea</p> <p>16 how that valsartan that was brought back</p> <p>17 to the market differed from the valsartan</p> <p>18 that Mylan had to recall?</p> <p>19 MR. REEFER: As acknowledged</p> <p>20 by the question itself, asked and</p> <p>21 answered.</p> <p>22 BY MR. DAVIS:</p> <p>23 Q. Is that a yes?</p> <p>24 A. Yes.</p>	<p style="text-align: right;">Page 316</p> <p>1 procures raw materials from a vendor, a</p> <p>2 raw material vendor, and that vendor is</p> <p>3 out of GMP compliance and the raw</p> <p>4 materials it's sending to Mylan are no</p> <p>5 good, it's ultimately Mylan's</p> <p>6 responsibility to adequately vet its</p> <p>7 vendors.</p> <p>8 Isn't that the FDA's</p> <p>9 position as stated in regulations, and</p> <p>10 GMP regulations specifically?</p> <p>11 MR. REEFER: Object to form.</p> <p>12 BY MR. DAVIS:</p> <p>13 Q. Do you have any</p> <p>14 understanding of that?</p> <p>15 MR. REEFER: Object to form.</p> <p>16 Beyond the scope of his report.</p> <p>17 Beyond the scope of my direct.</p> <p>18 But, I don't know, go ahead.</p> <p>19 THE WITNESS: Yes. Mylan</p> <p>20 would be responsible for their</p> <p>21 suppliers.</p> <p>22 MR. DAVIS: Okay. That's</p> <p>23 all the questions I have.</p> <p>24 MR. REEFER: So we'll go</p>
<p style="text-align: right;">Page 315</p> <p>1 Q. Okay. Last questions.</p> <p>2 Mr. Reefer asked you some</p> <p>3 questions about procurements of API, I</p> <p>4 believe, from multiple sources and how</p> <p>5 that might affect the quality or purity</p> <p>6 characteristics of the product.</p> <p>7 Do you remember that</p> <p>8 discussion with him?</p> <p>9 A. Yes.</p> <p>10 Q. Okay. Do you have an</p> <p>11 understanding that under FDA regulations</p> <p>12 that a manufacturer like Mylan is</p> <p>13 responsible for all of its suppliers?</p> <p>14 MR. REEFER: Object to form.</p> <p>15 Beyond the scope.</p> <p>16 THE WITNESS: That Mylan is</p> <p>17 responsible for all of their</p> <p>18 suppliers? And to what extent and</p> <p>19 to what regard?</p> <p>20 I think that's a -- like an</p> <p>21 unfinished question.</p> <p>22 BY MR. DAVIS:</p> <p>23 Q. Sure.</p> <p>24 If Mylan, for example,</p>	<p style="text-align: right;">Page 317</p> <p>1 huddle, and I'll come back to see</p> <p>2 if -- I'm just kidding, John.</p> <p>3 VIDEO TECHNICIAN: No more</p> <p>4 questions?</p> <p>5 MR. DAVIS: We can go off</p> <p>6 the record.</p> <p>7 MR. REEFER: No. I have --</p> <p>8 MR. DAVIS: Sorry, I take it</p> <p>9 back.</p> <p>10 MR. REEFER: I just had -- I</p> <p>11 just have maybe two questions,</p> <p>12 three questions.</p> <p>13 - - -</p> <p>14 EXAMINATION</p> <p>15 - - -</p> <p>16 BY MR. REEFER:</p> <p>17 Q. Dr. Sheinin, do you purport</p> <p>18 to offer any opinions with respect to</p> <p>19 whether Mylan complied with GMP</p> <p>20 regulations?</p> <p>21 A. No.</p> <p>22 Q. Do you intend to offer any</p> <p>23 opinion with respect to whether Mylan's</p> <p>24 investigation of unknown peaks, in some</p>

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1 form or fashion, complied with rules and
 2 regulations?
 3 A. No.
 4 Q. To your knowledge, did
 5 what's been described as Mylan Unit 7
 6 manufacture API -- API valsartan?
 7 A. I have no idea what Unit 7
 8 manufactures.
 9 MR. REEFER: All right. I
 10 think that's all I have.
 11 MR. DAVIS: No further
 12 questions.
 13 VIDEO TECHNICIAN: This
 14 marks the end of today's
 15 deposition. The time is 6:06 p.m.
 16 - - -
 17 (Whereupon, the deposition
 18 concluded at 6:06 p.m.)
 19 - - -
 20
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1 INSTRUCTIONS TO WITNESS
 2
 3 Please read your deposition
 4 over carefully and make any necessary
 5 corrections. You should state the reason
 6 in the appropriate space on the errata
 7 sheet for any corrections that are made.
 8 After doing so, please sign
 9 the errata sheet and date it.
 10 You are signing same subject
 11 to the changes you have noted on the
 12 errata sheet, which will be attached to
 13 your deposition.
 14 It is imperative that you
 15 return the original errata sheet to the
 16 deposing attorney within thirty (30) days
 17 of receipt of the deposition transcript
 18 by you. If you fail to do so, the
 19 deposition transcript may be deemed to be
 20 accurate and may be used in court.
 21
 22
 23
 24

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1 CERTIFICATE
 2
 3
 4 I, Amanda Maslinsky-Miller, Certified Realtime
 5 Reporter, do hereby certify that prior to the
 6 commencement of the examination, ERIC SHEININ,
 7 Ph.D., was remotely sworn by me to testify to
 8 the truth, the whole truth and nothing but the
 9 truth.
 10 I DO FURTHER CERTIFY that the foregoing is a
 11 verbatim transcript of the testimony as taken
 12 stenographically by me at the time, place and
 13 on the date hereinbefore set forth, to the best
 14 of my ability.
 15 I DO FURTHER CERTIFY that I am neither a
 16 relative nor employee nor attorney nor counsel
 17 of any of the parties to this action, and that
 18 I am neither a relative nor employee of such
 19 attorney or counsel, and that I am not
 20 financially interested in the action.
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1 ACKNOWLEDGMENT OF DEPONENT

2

3 I, _____, do
4 hereby certify that I have read the
5 foregoing pages, 1 - 318, and that the
6 same is a correct transcription of the
7 answers given by me to the questions
8 therein propounded, except for the
9 corrections or changes in form or
10 substance, if any, noted in the attached
11 Errata Sheet.

7

8

9 ERIC SHEININ, Ph.D. DATE _____

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11 Subscribed and sworn
12 to before me this

11

12 _____ day of _____, 20____.

12

13 My commission expires: _____

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15 Notary Public _____

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Page 323

1 LAWYER'S NOTES

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Exhibit 216

1 IN THE UNITED STATES DISTRICT COURT
2 DISTRICT OF NEW JERSEY
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4
5 IN RE: VALSARTAN)
 LOSARTAN, AND IRBESARTAN)
6 PRODUCTS LIABILITY)
 LITIGATION)
7)
) No. 2875
8)
) HON. ROBERT B. KUGLER
9 This Document Relates to)
 All Actions)
10)
)

11
12 CONFIDENTIAL INFORMATION
13 SUBJECT TO PROTECTIVE ORDER
14 REMOTE
15 VIDEO-RECORDED
16 EXPERT WITNESS TESTIMONY OF
17 ROGER WILLIAMS, M.D.

18
19 Thursday, February 17, 2022, 7:18 a.m.
20 - - - -

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24 REPORTED BY: ELAINA BULDA-JONES, CSR 11720
25

Page 2

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 20 BY: VICTORIA DAVIS LOCKARD, ESQ.
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 6 MR. STANOCH 320
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 14 Exhibit 2 Roger Williams, List of 11
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 18 Teva.net,
 19 TEVA-MDL2875-00565758 through
 20 00565764
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 for Industry

<p>Page 6</p> <p>1 Exhibit 7 Valsartan USP Monograph, 128 January 28, 2022</p> <p>2</p> <p>3 Exhibit 8 Impurities in Drug Products and Drug Substances - A USP 145 Approach, Ravi Ravichandran, Principal Scientific Liaison</p> <p>4</p> <p>5 Exhibit 9 Overview of USP General 152 Chapters <476> and <1086>, Prescription/Non-Prescription Stakeholder Forum, October 19, 2017</p> <p>6</p> <p>7 Exhibit 10 FDA's Overview of the Guidance 156 for Industry: Control of Nitrosamine Impurities in Human Drugs, David Keire, Ph.D., and Dongmei Lu, Ph.D., Office of Pharmaceutical Quality, October 2, 2020</p> <p>8</p> <p>9 Exhibit 11 E-mail, 06 July 2018, To: All, 165 From: Global Quality Compliance, Re: Lift of Hold Status for All Finished Products Manufactured using Valsartan API from Jubilant and Mylan</p> <p>10</p> <p>11 Exhibit 12 Generic Drug Manufacturer 210 Ranbaxy Pleads Guilty and Agrees to Pay \$500 Million to Resolve False Claims Allegations, cGMP Violations and False Statements to the FDA</p> <p>12</p> <p>13 Exhibit 13 Orange Book Preface 224</p> <p>14</p> <p>15 Exhibit 14 Expert: Nitrosamines 'Can Slip 256 Through the Manufacturing Process,' Making Reference Standards Essential to Avoid this Carcinogen in the Drug Supply Chain, June 29, 2021</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25 Exhibit 15 Invoices, 5 pages 270</p>	<p>Page 8</p> <p>1 THE VIDEOGRAPHER: Okay. We are now on</p> <p>2 the record.</p> <p>3 My name is Kristina Lee. I am a</p> <p>4 videographer for Golkow Litigation Services.</p> <p>5 Today's date is February 17th, 2022, and</p> <p>6 the time is 7:18 Pacific.</p> <p>7 This remote video deposition is being held</p> <p>8 in the matter of Valsartan, Losartan and Irbesartan</p> <p>9 Products Liability Litigation, MDL No. 2875, for the</p> <p>10 United States District Court, District of New</p> <p>11 Jersey. The deponent is Roger Williams.</p> <p>12 All parties to this deposition are</p> <p>13 appearing remotely and have agreed to the witness</p> <p>14 being sworn in remotely. Due to the nature of</p> <p>15 remote reporting, please pause briefly before</p> <p>16 speaking to ensure all parties are heard completely.</p> <p>17 All counsel will be noted on the</p> <p>18 stenographic record.</p> <p>19 The court reporter is Elaina Bulda-Jones,</p> <p>20 and she will now swear in the witness.</p> <p>21 ROGER WILLIAMS, M.D.,</p> <p>22 called as a witness by the Plaintiffs herein, being</p> <p>23 first duly sworn by the Certified Shorthand Reporter</p> <p>24 was thereupon examined and testified as is</p> <p>25 hereinafter set forth.</p>
<p>Page 7</p> <p>1 Exhibit 16 NDA Partners LLC, Curriculum 284 Vitae of Roger Williams, M.D., November 2021</p> <p>2</p> <p>3 Exhibit 17 Video 284</p> <p>4 Exhibit 18 Complete set of materials sent 292 to Dr. Williams</p> <p>5</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>Page 9</p> <p>1 THE REPORTER: Mr. Stanoch.</p> <p>2 MR. STANOCH: Thank you.</p> <p>3 EXAMINATION</p> <p>4 BY MR. STANOCH:</p> <p>5 Q. Good morning, Dr. Williams.</p> <p>6 A. Good morning, Mr. Stanoch.</p> <p>7 Q. Could you tell us where you are located</p> <p>8 today?</p> <p>9 A. I'm in San Francisco, California, in 4</p> <p>10 Embarcadero Center in the offices of Greenberg</p> <p>11 Taurig.</p> <p>12 Q. Thank you.</p> <p>13 And other than Teva's counsel, Ms. Lockard</p> <p>14 and Mr. Harkins, and perhaps any tech people, are</p> <p>15 there anybody else in the room with you?</p> <p>16 A. No, there are not.</p> <p>17 Q. Other than a box which we have yet to open</p> <p>18 of potential documents that we sent to your counsel,</p> <p>19 do you have any documents with you in your room?</p> <p>20 A. I see three documents that my counsel has</p> <p>21 put before me. One is the report, one is the</p> <p>22 materials considered, and one is the deposition</p> <p>23 request.</p> <p>24 Q. Perfect. Anything else?</p> <p>25 A. I have a blank pad of paper and a pen, and</p>

<p style="text-align: right;">Page 10</p> <p>1 nothing else.</p> <p>2 Q. Thank you.</p> <p>3 Now, you have been deposed a number of</p> <p>4 times before; is that fair?</p> <p>5 A. That's true, Mr. Stanoch.</p> <p>6 Q. Right. So you understand the general</p> <p>7 rules we will be following here today, that I will</p> <p>8 be asking you a series of questions, you'll be</p> <p>9 providing answers, everything everyone says on the</p> <p>10 record will be taken down by the stenographer and on</p> <p>11 the video; you understand that?</p> <p>12 A. I do.</p> <p>13 Q. Right. And if you do not understand the</p> <p>14 question, I ask, please tell me; otherwise I will</p> <p>15 assume you understand; is that fair?</p> <p>16 A. That's fair.</p> <p>17 Q. Do you understand you should answer the</p> <p>18 question unless your counsel instructs you</p> <p>19 otherwise?</p> <p>20 A. I do understand that.</p> <p>21 Q. Is there any reason why you cannot testify</p> <p>22 truthfully and accurately today?</p> <p>23 A. There is no reason.</p> <p>24 Q. Excellent. Let's do some housekeeping</p> <p>25 with exhibits, Dr. Williams. First, before we get</p>	<p style="text-align: right;">Page 12</p> <p>1 correct?</p> <p>2 A. Yes, I do, Mr. Stanoch.</p> <p>3 Q. Very good. And as a housekeeping matter,</p> <p>4 Dr. Williams, could you tell us what revisions were</p> <p>5 made in the copy of your report that we have marked</p> <p>6 as Exhibit 1 over the report that was originally</p> <p>7 provided on January 12th, 2022?</p> <p>8 A. Yes. There were two references that</p> <p>9 needed to be changed.</p> <p>10 One was a reference to a guidance of FDA</p> <p>11 that talks about drug substances for ANDAs. In the</p> <p>12 unrevised report, that was not provided, so we have</p> <p>13 now provided that guidance. And it's listed in the</p> <p>14 materials considered as well as cited in my report.</p> <p>15 And I'll be glad to answer questions about that</p> <p>16 guidance if you wish, Mr. Stanoch.</p> <p>17 The other change was a reference to a USP</p> <p>18 guidance that talks about submitting requests for</p> <p>19 revisions to the United States Pharmacopeia-National</p> <p>20 Formulary. And the reason for the change was when I</p> <p>21 looked at it recently, it spoke to requests for</p> <p>22 revisions of dietary supplements, which of course is</p> <p>23 not pertinent in this matter. So we changed it to</p> <p>24 requests for revisions for chemical substances, and</p> <p>25 that is now referenced in the revised report and</p>
<p style="text-align: right;">Page 11</p> <p>1 going, I am going to mark as Williams 1 the revised</p> <p>2 expert report that your counsel provided to us 20 or</p> <p>3 so minutes ago.</p> <p>4 MR. STANOCH: Stand by, everyone.</p> <p>5 (Whereupon, Exhibit 1 was marked for</p> <p>6 identification.)</p> <p>7 BY MR. STANOCH:</p> <p>8 Q. So, Dr. Williams, the copy of your report</p> <p>9 in front of you given to you by your counsel, we</p> <p>10 will call that Exhibit 1, and for everyone else's</p> <p>11 benefit, it's available as Exhibit 1 on the</p> <p>12 electronic shared files. Are you good with that,</p> <p>13 Doctor?</p> <p>14 A. I am.</p> <p>15 Q. Excellent. I am going to mark also the</p> <p>16 revised list of the materials you considered that</p> <p>17 your counsel also provided a little earlier this</p> <p>18 morning. Stand by.</p> <p>19 (Whereupon, Exhibit 2 was marked for</p> <p>20 identification.)</p> <p>21 BY MR. STANOCH:</p> <p>22 Q. Exhibit 2, Dr. Williams, that's the list</p> <p>23 of materials considered that were provided to us 20</p> <p>24 or so minutes ago. You have a physical copy in</p> <p>25 front of you, I understand, from your counsel,</p>	<p style="text-align: right;">Page 13</p> <p>1 also in the materials considered. Again, I'll be</p> <p>2 glad to answer questions about that document if you</p> <p>3 wish, Mr. Stanoch.</p> <p>4 And then there were two additional</p> <p>5 documents that were important to my report relating</p> <p>6 to the Orange Book, and those were not listed in the</p> <p>7 materials considered, so we adjusted the materials</p> <p>8 considered to include those references. One was an</p> <p>9 Orange Book from January 2019 summarizing the prior</p> <p>10 year, 2018. And then the other Orange Book</p> <p>11 reference was the Orange Book Supplement No. 8,</p> <p>12 August for 2018, and those are both referenced in my</p> <p>13 report and also now listed in the materials</p> <p>14 considered.</p> <p>15 Q. Okay. Thank you, Doctor.</p> <p>16 And regarding your report first, I believe</p> <p>17 the particular footnotes that were updated with the</p> <p>18 two materials you noted, those are Footnotes 20 and</p> <p>19 21 of page 17 of your report; is that right?</p> <p>20 A. Let me take a quick look just to confirm.</p> <p>21 Yes, you have it exactly right, Mr. Stanoch.</p> <p>22 Q. Very good. And the materials considered,</p> <p>23 the two Orange Book references that are now listed</p> <p>24 in your revised materials considered, I believe it's</p> <p>25 your testimony that you had relied on them in</p>

<p>Page 14</p> <p>1 preparing your report, they just didn't make it into 2 the reliance materials initially; is that fair? 3 A. Yes, the materials considered listing. 4 But they were referenced in my report appropriately 5 and cited. 6 Q. Understood. And do you happen to have the 7 page of the reliance materials where the two Orange 8 Book sources are now listed? 9 A. I'm sure I do, but it might help me if we 10 agree on what page that is. 11 Q. I think it may be page 2, but if you 12 cannot do it quickly, Doctor, we can certainly take 13 care of it at a break. I don't think there is a 14 controversy on this. 15 A. Oh, yeah, there it is. It's under 16 "Regulatory Guidances, Standards, and Documents," 17 and there is a 2019 Orange Book, which is the second 18 listing in that category, and then the 2018 Orange 19 Book, Cumulative Supplement 8, August 2018, which is 20 the third listing. 21 MR. HARKINS: Did we lose Mr. Stanoch? 22 THE WITNESS: Oh, I think he is looking at 23 the materials considered. 24 (Whereupon, a brief discussion off the 25 record.)</p> <p>Page 15</p> <p>1 THE VIDEOGRAPHER: Okay. We're going off 2 the record. The time is 7:29. 3 (Whereupon, a brief recess was taken.) 4 THE VIDEOGRAPHER: Okay. We're coming 5 back on the record. The time on the video monitor 6 is 7:37. Please begin. 7 BY MR. STANOCH: 8 Q. Okay. Doctor, thank you for bearing with 9 us with the technical issues. I believe we were 10 just looking at your revised reliance materials, 11 correct, that's where we were? 12 A. Yes, I understand. 13 Q. Uh-huh. And you were showing us, you 14 know, the two Orange Book sources that are now 15 listed under the "Regulatory Guidances" heading, I 16 believe it was, right? 17 A. Yes. 18 Q. All right. Other than the updates of 19 Footnotes 20 and 21 of your report, does the revised 20 report that's been produced today have any other 21 changes to it over your original January 12th, 2022, 22 report? 23 A. No, it does not. 24 Q. Okay. Thank you. 25 A. There is a new signature page,</p>	<p>Page 16</p> <p>1 Mr. Stanoch, with today's date. 2 Q. Understood. Other than the two footnote 3 revisions we discussed and the new signature page, 4 are there any other changes in your report, now 5 dated February 17th, 2022, over the original 6 iteration of your report from January 12th, 2022? 7 A. No, there are not. 8 Q. Okay. And on your lists of materials 9 considered, I think there were a few other things 10 that were added between your original lists from 11 January 12th and today besides the two Orange Book 12 sources. And do you recall that generally, sir? 13 A. No, actually I can't say I do, 14 Mr. Stanoch. 15 Q. That's fine. And, you know, for instance, 16 if you look at page 1 of Exhibit 2, your latest 17 iteration of materials considered, there is now a 18 section that says, "Defendants' Expert Reports (with 19 exhibits)." Do you see that? 20 A. Page 1? Oh, yes, I do see that. 21 Q. Right. And the first line is the report 22 of Timothy Anderson. Do you see that? 23 A. I do see that. 24 Q. And then it continues on, correct? 25 A. Yes.</p> <p>Page 17</p> <p>1 Q. And you could say it in your own words, 2 but it looks like your revised materials here of 3 2/17/2022 is showing that you have now reviewed all 4 of the other defense expert reports listed here, 5 whereas you had not reviewed them at the time you 6 rendered your original report of January 12th, 2022; 7 is that right? 8 A. Yes. I think I did not see these expert 9 reports before I concluded my January 12th report. 10 Q. Uh-huh. Okay. And so the -- 11 MS. LOCKARD: And just for the record, 12 Dave, the list updating the list of materials with 13 the new expert report was included in the 2/15 14 production. So just, I think, to clarify, you have 15 received -- prior version that did have the expert 16 reports listed. 17 MR. STANOCH: No, I agree, Counsel. And 18 this isn't controversial. It's just more 19 housekeeping. 20 MS. LOCKARD: Right. 21 BY MR. STANOCH: 22 Q. But I just wanted to establish, 23 Dr. Williams, that as of the date of your original 24 January 12th, 2022, report, you had not reviewed any 25 defense expert reports in this case, right?</p>
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<p style="text-align: right;">Page 18</p> <p>1 A. That's true.</p> <p>2 Q. And since then, you did review them all at</p> <p>3 some point, correct?</p> <p>4 A. Well, what I would say --</p> <p>5 MS. LOCKARD: Objection. Form.</p> <p>6 THE WITNESS: -- is I looked at all of</p> <p>7 them, and some of them I looked at more carefully</p> <p>8 than others.</p> <p>9 MS. LOCKARD: All of them on the list.</p> <p>10 THE WITNESS: All of them on the list,</p> <p>11 yes.</p> <p>12 BY MR. STANOCH:</p> <p>13 Q. And because you looked at the defense</p> <p>14 expert reports on the list we're looking at in</p> <p>15 Exhibit 2 after you issued your original report, is</p> <p>16 it fair to say that you did not rely on any defense</p> <p>17 expert report in rendering your January 12th, 2022,</p> <p>18 opinions?</p> <p>19 A. That's accurate, Mr. Stanoch. Thank you.</p> <p>20 Q. Right. And further, because you only</p> <p>21 noted two changes, to Footnotes 20 and 21, in your</p> <p>22 report dated today, did anything in the defense</p> <p>23 expert reports listed here in Exhibit 2 alter or</p> <p>24 change your opinions as they were originally</p> <p>25 expressed in your January 12th, 2022, report?</p>	<p style="text-align: right;">Page 20</p> <p>1 original January 12th report to your February 17th</p> <p>2 report, right?</p> <p>3 A. No, I have not changed my opinions at all.</p> <p>4 Q. Very good. Thank you, Doctor. Let's put</p> <p>5 that aside, and if there is other sort of</p> <p>6 housekeeping things with the reliance materials, we</p> <p>7 can hit it later, okay?</p> <p>8 A. Thank you.</p> <p>9 Q. So, Doctor, your report -- and we will use</p> <p>10 Exhibit 1, which is the one dated February 17th,</p> <p>11 2022, this report includes all opinions you are</p> <p>12 currently offering in this matter, correct?</p> <p>13 A. Yes.</p> <p>14 Q. At this time, do you intend to offer any</p> <p>15 other opinions in this matter besides those</p> <p>16 reflected in your report, Exhibit 1?</p> <p>17 A. No.</p> <p>18 MS. LOCKARD: I'm going to object to that,</p> <p>19 as it calls for attorney work product. Obviously we</p> <p>20 reserve the right to use Dr. Williams in the</p> <p>21 liability portion and for liability opinions, but he</p> <p>22 is not intending to give those opinions today.</p> <p>23 Court Reporter, can you hear me?</p> <p>24 THE REPORTER: Yes, ma'am.</p> <p>25 MR. STANOCH: I heard you too,</p>
<p style="text-align: right;">Page 19</p> <p>1 A. No, nothing at all.</p> <p>2 Q. It also appears, Doctor, looking at</p> <p>3 Exhibit 2, your reliance materials list of today,</p> <p>4 page 2, you see "Deposition Transcripts"? Do you</p> <p>5 see that?</p> <p>6 A. Yes, I do.</p> <p>7 Q. All right. And I believe you now list</p> <p>8 four entries there, beginning with, "Transcript of</p> <p>9 Edward Kaplan," through "Transcript of Ron Najafi</p> <p>10 Deposition"; do you see those four entries?</p> <p>11 A. I do.</p> <p>12 Q. Right. And those were not listed in your</p> <p>13 original reliance materials in January 12th, 2022,</p> <p>14 right, because these transcripts postdated your</p> <p>15 report; is that fair?</p> <p>16 A. Exactly. You can see that from the date</p> <p>17 in the first part of each entry.</p> <p>18 Q. Absolutely right. And my only point is</p> <p>19 going to be, Doctor, is that you did not rely on the</p> <p>20 transcripts of Edward Kaplan, Kali Panagos, John</p> <p>21 Quick or Ron Najafi in rendering your January 12th,</p> <p>22 2022, opinions, correct?</p> <p>23 A. That's correct.</p> <p>24 Q. And nothing in those four transcripts have</p> <p>25 led you to change or alter your opinions from your</p>	<p style="text-align: right;">Page 21</p> <p>1 Ms. Lockard.</p> <p>2 MS. LOCKARD: Okay.</p> <p>3 MR. STANOCH: I had nothing to respond to.</p> <p>4 MS. LOCKARD: Okay. No problem. I just</p> <p>5 didn't see it come up on the realtime, so I thought</p> <p>6 maybe we had lost someone, but I see it now.</p> <p>7 BY MR. STANOCH:</p> <p>8 Q. Doctor, you reference, you know, this</p> <p>9 litigation by caption in Paragraph 2 of your report,</p> <p>10 right?</p> <p>11 A. I'm looking at Paragraph -- "I make this</p> <p>12 disclosure," is that what you are talking about,</p> <p>13 Mr. Stanoch?</p> <p>14 Q. Yes, sir. Yes, sir.</p> <p>15 A. Yes, that's correct.</p> <p>16 Q. And what is your understanding, generally,</p> <p>17 of this litigation, sir?</p> <p>18 A. It relates to the presence of nitrosamine</p> <p>19 impurities, in terms of my report, in Tab 4, ANDAs</p> <p>20 that were approved by FDA for Teva. And there are</p> <p>21 of course many ramifications to that statement, but</p> <p>22 I'll stop there in terms of what my report focuses</p> <p>23 on.</p> <p>24 Q. And you can look at your reliance</p> <p>25 materials, Doctor, but I believe you did not review</p>

<p style="text-align: right;">Page 22</p> <p>1 any plaintiff-specific discovery materials, did you?</p> <p>2 A. I'm not sure I understand your question.</p> <p>3 Can you point out what you are talking about on my</p> <p>4 materials-considered list?</p> <p>5 Q. Sure. You did not review any transcripts</p> <p>6 of any plaintiffs in this litigation, correct?</p> <p>7 A. As part of my report?</p> <p>8 Q. Correct.</p> <p>9 A. Yes, I was speaking particularly in my</p> <p>10 report about the expert report of Dr. Panagos,</p> <p>11 Mr. Quick, and Dr. Najafi. But as I already said, I</p> <p>12 did not rely on the transcript of the deposition to</p> <p>13 inform my opinions. I was looking more at their</p> <p>14 expert reports.</p> <p>15 Q. Understood, Doctor. You did not review</p> <p>16 any transcripts of depositions taken of any</p> <p>17 plaintiff, as opposed to a plaintiff expert, in this</p> <p>18 litigation, correct?</p> <p>19 A. You know, plaintiffs' expert reports, I'm</p> <p>20 looking at my materials considered, and I think the</p> <p>21 answer to that question is yes. I did not review</p> <p>22 plaintiffs' depositions.</p> <p>23 Q. Okay. You did not --</p> <p>24 A. If I am answering -- yeah. If I am</p> <p>25 answering your question correctly, Mr. Stanoch.</p>	<p style="text-align: right;">Page 24</p> <p>1 but I wouldn't be able to safely say it was --</p> <p>2 Mr. Stanoch, does that help?</p> <p>3 BY MR. STANOCH:</p> <p>4 Q. Well, again, Dr. Williams, this is not</p> <p>5 trying to be a gotcha. I don't see in your reliance</p> <p>6 materials, for example, any Bates number for a</p> <p>7 document that a plaintiff produced the documents.</p> <p>8 And I just want to confirm, then, you did not look</p> <p>9 at any documents that were Bates-stamped as being</p> <p>10 produced from plaintiffs.</p> <p>11 A. I think I can agree with that unless my</p> <p>12 counsel wishes to object.</p> <p>13 MS. LOCKARD: No. I assume you are</p> <p>14 talking about discovery documents. And obviously</p> <p>15 there are plaintiff pleadings and disclosures and</p> <p>16 then whatnot on the list, but --</p> <p>17 MR. STANOCH: Yes, that's right. And my</p> <p>18 questions were about discovery materials, Counsel,</p> <p>19 you know, right. Right.</p> <p>20 Q. And, Dr. Williams, again, so you did not</p> <p>21 review, for example, copies of individual plaintiff</p> <p>22 pharmacy records that any given plaintiff might have</p> <p>23 produced, right? You don't recall seeing any of</p> <p>24 that, right?</p> <p>25 A. No, you are correct, Mr. Stanoch.</p>
<p style="text-align: right;">Page 23</p> <p>1 Please help me if you think I didn't.</p> <p>2 Q. No, this is not a trick question,</p> <p>3 Dr. Williams. I agree with you that nowhere in your</p> <p>4 reliance materials do you list transcripts of</p> <p>5 depositions taken of a plaintiff, as opposed to a</p> <p>6 plaintiff expert, so I just wanted to make sure my</p> <p>7 understanding was correct. And it sounds like we</p> <p>8 are in accord, right?</p> <p>9 A. Yes. Yes. I think we're in agreement</p> <p>10 now. One of the reasons I was struggling, I was</p> <p>11 trying to look for something that wasn't on the</p> <p>12 list, and that's a little difficult.</p> <p>13 Q. Of course. And you did not review any</p> <p>14 documents produced by any plaintiff in this</p> <p>15 litigation, correct?</p> <p>16 MS. LOCKARD: And I'll just make the</p> <p>17 objection that I'll say it's vague and confusing</p> <p>18 because I don't know that Dr. Williams knows who</p> <p>19 produced what. But, I mean, I don't want to answer</p> <p>20 the question for him, but --</p> <p>21 THE WITNESS: Well, yeah, I think</p> <p>22 Ms. Lockard is stating it correctly. I don't know</p> <p>23 what was produced by plaintiffs. But I find it hard</p> <p>24 to believe that they wouldn't have produced some of</p> <p>25 the material that also came to me from my counsel,</p>	<p style="text-align: right;">Page 25</p> <p>1 Q. Right. And you don't recall ever</p> <p>2 reviewing any medical records that a particular</p> <p>3 plaintiff might have produced in this litigation,</p> <p>4 correct?</p> <p>5 A. I did not.</p> <p>6 Q. Uh-huh. And you don't recall reviewing</p> <p>7 any insurance materials that any particular</p> <p>8 plaintiff might have produced in this litigation,</p> <p>9 correct?</p> <p>10 A. I did not.</p> <p>11 Q. Uh-huh. Do your opinions in this case</p> <p>12 depend on the number of the potential plaintiffs in</p> <p>13 the litigation?</p> <p>14 A. No.</p> <p>15 Q. Right. If this litigation involved one</p> <p>16 plaintiff or 10,000 plaintiffs, your opinions as</p> <p>17 expressed in your report would be the same, correct?</p> <p>18 A. Yes.</p> <p>19 Q. Were you asked to assume by counsel</p> <p>20 anything for purposes of your report, sir?</p> <p>21 A. No, I was not.</p> <p>22 Q. Were you asked to assume that Teva's</p> <p>23 finished-dose valsartan products contained any</p> <p>24 nitrosamines?</p> <p>25 A. Was I asked to make that assumption? No,</p>

<p style="text-align: right;">Page 26</p> <p>1 I was not asked to make that assumption.</p> <p>2 Q. Do you have any opinion on whether Teva's</p> <p>3 finished-dose products did contain nitrosamines?</p> <p>4 MS. LOCKARD: Outside the scope of his</p> <p>5 report. Objection.</p> <p>6 THE WITNESS: My understanding is that FDA</p> <p>7 asked Teva to test some samples of their finished --</p> <p>8 of their drug product manufactured under the four</p> <p>9 ANDAs and that Teva did supply that information to</p> <p>10 FDA. But it's not something I cited to in my</p> <p>11 report.</p> <p>12 BY MR. STANOCH:</p> <p>13 Q. Uh-huh. So you don't know one way or the</p> <p>14 other whether Teva's finished-dose valsartan</p> <p>15 products contained nitrosamines?</p> <p>16 MS. LOCKARD: Objection. Vague.</p> <p>17 I think if you want to ask him if he has</p> <p>18 personal knowledge, that would be a better question.</p> <p>19 THE WITNESS: Well, in any case, I do</p> <p>20 recall seeing some numbers that Teva provided to</p> <p>21 FDA, but they are not in my report and I don't</p> <p>22 recollect them now.</p> <p>23 BY MR. STANOCH:</p> <p>24 Q. Uh-huh. And you are not opining, are you,</p> <p>25 Doctor, on the levels of nitrosamines that may or</p>	<p style="text-align: right;">Page 28</p> <p>1 impurity. After approval, it depends on a number of</p> <p>2 factors, including -- I'm sorry, Mr. Stanoch. Were</p> <p>3 you asking generally about impurities, genotoxic</p> <p>4 impurities, or nitrosamine impurities?</p> <p>5 BY MR. STANOCH:</p> <p>6 Q. Potential genotoxic impurities generally,</p> <p>7 not specific to nitrosamines at this question.</p> <p>8 A. Okay. Good. I would say after approval,</p> <p>9 if such an impurity is discovered, I think there</p> <p>10 would be an attempt to work with FDA for a marketed</p> <p>11 drug in the United States to determine what the</p> <p>12 limit should be and what corrective action should</p> <p>13 need to be taken.</p> <p>14 Q. Uh-huh. Should a API manufacturer who</p> <p>15 becomes aware of a potential genotoxic impurity in</p> <p>16 API notify their customers who buy that API?</p> <p>17 MS. LOCKARD: Objection. Outside the</p> <p>18 scope of Dr. Williams' class-certification report</p> <p>19 opinions and gets into the liability issue.</p> <p>20 THE WITNESS: Well, I'm thinking of the</p> <p>21 specific example in this matter where, yes, you</p> <p>22 know, the API manufacturer did inform customers. So</p> <p>23 I would say that is a good practice in my personal</p> <p>24 opinion.</p> <p>25</p>
<p style="text-align: right;">Page 27</p> <p>1 may not have been in Teva's finished-dose products,</p> <p>2 correct?</p> <p>3 A. No, I'm not.</p> <p>4 Q. Uh-huh. Were you asked to assume by</p> <p>5 counsel that Teva's finished-dose products did not</p> <p>6 contain nitrosamines?</p> <p>7 A. No, I was not.</p> <p>8 Q. Uh-huh. Were you asked to assume that</p> <p>9 Teva had no knowledge about the chemical synthesis</p> <p>10 processes necessary to create valsartan API?</p> <p>11 A. I was not asked to make that assumption.</p> <p>12 Q. Okay. Right. You were not asked to make</p> <p>13 any assumptions in rendering your opinions, correct?</p> <p>14 A. Yes, that's correct.</p> <p>15 Q. Okay. When an API manufacturer becomes</p> <p>16 aware of a potential genotoxic impurity, sir, what</p> <p>17 should they do?</p> <p>18 MS. LOCKARD: Objection. Form. Outside</p> <p>19 the scope -- his report and the class-certification</p> <p>20 phase.</p> <p>21 THE WITNESS: The way I would answer that,</p> <p>22 Mr. Stanoch, is it depends on when the discovery was</p> <p>23 made. If it is during the development process,</p> <p>24 prior to approval of either the NDA or ANDA, a</p> <p>25 company may be able to mitigate the presence of the</p>	<p style="text-align: right;">Page 29</p> <p>1 BY MR. STANOCH:</p> <p>2 Q. You mentioned in your answer the API</p> <p>3 manufacturer did inform customers here. What do you</p> <p>4 mean?</p> <p>5 A. Well, if I understand the history in this</p> <p>6 matter, Princeton, which is a company associated with</p> <p>7 ZHP in China, did inform FDA that they were finding</p> <p>8 the NDMA nitrosamine impurity, and I think in turn</p> <p>9 then FDA began working with the various</p> <p>10 manufacturers using the ZHP drug substance.</p> <p>11 Q. Uh-huh. When, to your recollection, did</p> <p>12 ZHP become aware of the potential nitrosamine</p> <p>13 impurities in valsartan API that you alluded to in</p> <p>14 your prior answer?</p> <p>15 MS. LOCKARD: Objection. Speculation.</p> <p>16 THE WITNESS: I think we can look at my</p> <p>17 report.</p> <p>18 BY MR. STANOCH:</p> <p>19 Q. Sure.</p> <p>20 A. Is it all right if I look at my report</p> <p>21 now, Mr. Stanoch?</p> <p>22 Q. Of course, Doctor.</p> <p>23 A. I would say when this became generally</p> <p>24 known to the public was July 13th, 2018, with the</p> <p>25 first FDA press release. And FDA noted in the press</p>

<p style="text-align: right;">Page 30</p> <p>1 release that their understanding came from Princeton 2 Pharmaceuticals, as I said, which in turn, became 3 aware of the impurity through the efforts of ZHP. 4 And when we are talking about the impurity, we are 5 talking about NDMA. 6 Q. Okay. What paragraph are you looking at, 7 Doctor, so we can be on the same page? 8 A. It's Paragraph 92. 9 Q. Right. And this is the July 13, 2018, 10 reference to an FDA press release about NDMA in the 11 ZHP valsartan API. My question was: When do you 12 recall that ZHP became aware of the NDMA impurity in 13 the valsartan API? 14 MS. LOCKARD: Objection. Form. 15 Speculation. 16 THE WITNESS: Yes, I don't think I have 17 that information in my report or that I cited to it. 18 BY MR. STANOCH: 19 Q. You don't know when ZHP discovered the 20 potential NDMA impurity in valsartan API? 21 MS. LOCKARD: Same objection. Asked and 22 answered as well. 23 THE WITNESS: I don't think I stated it in 24 my report, Mr. Stanoch. 25</p>	<p style="text-align: right;">Page 32</p> <p>1 as vague to the extent you are asking about 2 potential genotoxic impurities. 3 MR. STANOCH: How would you like me to fix 4 the question, Counsel? 5 MS. LOCKARD: Well, if you are asking 6 about nitrosamines, the presence of nitrosamines, 7 that's more specific than potential genotoxic 8 impurities. 9 MR. STANOCH: Okay. I withdraw my prior 10 question. 11 Q. Doctor, when did Teva become aware of the 12 potential nitrosamine contamination in valsartan 13 API? 14 A. It was around the time Teva put on hold 15 the manufacture of its four ANDAs because of the 16 presence of these impurities in the ZHP drug 17 substance. 18 Q. Uh-huh. And when -- 19 A. And that, I believe, was in June of 2018. 20 Then there were a number of activities that Teva 21 undertook, which of course is a core part of my 22 report, but the most important one in terms of my 23 report were the recalls of the products that 24 contained the ZHP drug substance. 25 Q. Okay. Should a drug manufacturer such as</p>
<p style="text-align: right;">Page 31</p> <p>1 BY MR. STANOCH: 2 Q. Don't you think it would be important for 3 you to know when ZHP became aware of the potential 4 for NDMA impurities in valsartan API in rendering 5 your opinions? 6 MS. LOCKARD: Objection. Argumentative. 7 THE WITNESS: Remember, I'm speaking to 8 Teva, so, you know, for the most part, I don't focus 9 on ZHP. I'm talking about Teva's actions in the 10 context of the finding of nitrosamine impurities. 11 BY MR. STANOCH: 12 Q. Wouldn't you need to know, sir, when ZHP 13 became aware of the NDMA in valsartan API to assess 14 when Teva, as the customer, should have known about 15 that as well? 16 A. No, I don't believe so. I think Teva was 17 aware in the weeks before the FDA press release. 18 But again, my focus is on Teva's activities and what 19 they did when they became aware of the presence of 20 nitrosamine impurities in the ZHP drug substance. 21 Q. Let's focus on Teva. When did Teva learn 22 of the potential for NDMA genotoxic impurities in 23 valsartan API? 24 A. Well -- 25 MS. LOCKARD: I'm going to object to that</p>	<p style="text-align: right;">Page 33</p> <p>1 Teva have quality systems in place to ensure that 2 its API suppliers notify them upon the discovery of 3 potential genotoxic impurities? 4 MS. LOCKARD: Objection. Outside the 5 scope of the class-certification expert report. 6 THE WITNESS: Yes, I did not comment on 7 that in my report. If you are asking me as a 8 personal question, I could say I would think it 9 likely that Teva would have that kind of agreement 10 or understanding. 11 BY MR. STANOCH: 12 Q. Uh-huh. Did you undertake to assess 13 whether that agreement or understanding existed here 14 between Teva and ZHP for valsartan API? 15 A. No, that was not part of my report or my 16 opinions. 17 MS. LOCKARD: Objection. That's outside 18 the scope of the expert report on 19 class-certification issues. 20 BY MR. STANOCH: 21 Q. Isn't it a finished-dose manufacturer's 22 responsibility to obtain material information about 23 genotoxic impurities from their API source in a 24 timely manner? 25 MS. LOCKARD: Objection. It's liability</p>

<p style="text-align: right;">Page 34</p> <p>1 question. It's outside the scope of the 2 class-classification expert report opinions. 3 MR. STANOCH: Counsel, you have said 4 outside the scope and liability issue a number of 5 times. Could you just -- I'm not picking a fight. 6 I just want to know what you mean by that. 7 MS. LOCKARD: Well, okay. We are in the 8 class-certification phase of the case, correct? 9 There are opinions that are very specific that have 10 been directed by Dr. Williams in his report. These 11 are not liability opinions. 12 The majority of your questions so far this 13 morning have been, what should manufacturers do? 14 What should their quality systems be? And they are 15 all liability opinions, and that is not the 16 substance of his report. That's not within his 17 report. These are squarely liability questions. 18 MR. STANOCH: Well, I appreciate that, 19 Ms. Lockard. I'll just say I don't necessarily 20 agree with you that these are outside the scope of 21 the report that he has issued at class, but I'll 22 note your objection and we can keep going. 23 I'm sorry, Madam Reporter. Would you be 24 kind enough? Did I have a question pending? 25 THE REPORTER: Let me check for you.</p>	<p style="text-align: right;">Page 36</p> <p>1 The next question: What common evidence 2 would you need to look at to determine whether it is 3 a finished-dose manufacturer's responsibility to 4 obtain important information about genotoxic 5 impurities from their API source in a timely 6 fashion? 7 MS. LOCKARD: Objection. Vague. 8 Confusing. Outside the scope of the 9 class-certification expert report. 10 Did you say common evidence? Or I might 11 have misheard you. 12 THE WITNESS: Are you waiting for 13 Mr. Stanoch to answer, Ms. Lockard? 14 MS. LOCKARD: It's okay. I was, but I 15 have the -- I see on the transcript what he said. 16 All right. I stand by the objection. 17 THE WITNESS: You know, the way I would 18 answer it, Mr. Stanoch, it's a very general 19 question. It's probably more important to focus on 20 nitrosamine impurities because that's what my report 21 focuses on. 22 And all I can say is FDA at many points in 23 this episode said that the finding of these 24 genotoxic nitrosamine impurities was unexpected. So 25 I don't think I can speculate as to when either a</p>
<p style="text-align: right;">Page 35</p> <p>1 MR. STANOCH: Thank you. 2 (Whereupon, the reporter read the record 3 as follows: 4 "Question: Isn't it a finished-dose 5 manufacturer's responsibility to obtain material 6 information about genotoxic impurities from their 7 API source in a timely manner?") 8 MS. LOCKARD: Same objection. 9 THE WITNESS: You know, the understanding 10 that a drug substance and the corresponding drug 11 product may have genotoxic impurities has been a 12 challenge to FDA and the pharmaceutical industry 13 over many years. The FDA guidance that spoke to how 14 to deal with that actually came out in 2015. 15 So when you ask a general question like 16 that, it's very difficult for me to answer. But 17 definitely if the manufacturer of a drug product 18 feels there could be a genotoxic impurity, there is 19 an obligation to work with FDA to understand that 20 and to limit it if necessary. 21 I hope that's responsive to your question, 22 Mr. Stanoch. 23 BY MR. STANOCH: 24 Q. Partially, but I appreciate you trying, 25 Dr. Williams. I really do.</p>	<p style="text-align: right;">Page 37</p> <p>1 drug-substance manufacturer or a dosage-form 2 manufacturer would expect something that was -- or 3 anticipate something that was unexpected. I think 4 it's important to keep in mind that these impurities 5 were unexpected. 6 BY MR. STANOCH: 7 Q. Are you finished, Doctor? 8 A. Yes. 9 Q. Thank you. 10 I may ask you that from time to time, just 11 for the video, to make sure I don't step over you 12 and vice versa; is that okay? 13 A. Yes, no problem, Mr. Stanoch. 14 Q. Thank you. I appreciate your patience 15 there. 16 You said "unexpected" a number of times in 17 your answer there, and we will certainly get to 18 that. But let me -- you said that my question would 19 be different if I asked about nitrosamines versus 20 genotoxic impurities generally, so I'm going to ask 21 you the question differently. 22 Question: What evidence would you need to 23 look at in order to determine whether it is a 24 finished-dose manufacturer's responsibility to 25 obtain important information about nitrosamine</p>

<p style="text-align: right;">Page 38</p> <p>1 impurities from their API source in a timely 2 fashion? 3 MS. LOCKARD: Objection. Vague. 4 Confusing. Outside the scope of the 5 class-certification expert report. 6 THE WITNESS: You know, it might be 7 helpful, Mr. Stanoch, to back up a little bit on 8 what are the responsibilities of an ANDA filer in 9 terms of assessing impurities in its drug substance 10 and its drug product. 11 The presence of genotoxic impurities I 12 would say doesn't really come up too often in that 13 primary responsibility. So I think you are asking 14 for something that, if I may say so, is not routine 15 as part of the ANDA requirements or recommendations 16 by FDA. 17 BY MR. STANOCH: 18 Q. Are you saying it's not the responsibility 19 of a drug-product manufacturer to identify potential 20 genotoxic impurities? 21 MS. LOCKARD: Objection. Clearly outside 22 the scope of the class-certification opinions in the 23 expert report. It's clearly a liability question. 24 MR. STANOCH: This is his last answer, 25 Counsel.</p>	<p style="text-align: right;">Page 40</p> <p>1 Q. Was there any industry guidance on 2 genotoxic impurities prior to 2015, Doctor? 3 A. I think if we look at my report, I could 4 find reference to other documents that had been 5 produced by FDA or the EMA or in ICH, so -- and 6 those documents preceded the 2015 guidance. 7 Q. Do you agree that a drug-product 8 manufacturer is ultimately responsible for the API 9 that it incorporates into its finished-dose product? 10 A. Yes, I think that's generally a fair 11 statement, Mr. Stanoch. 12 Q. Yeah. So Teva is ultimately responsible 13 for the valsartan API that was in its finished-dose 14 valsartan product, correct? 15 A. Yes, I think I can agree with that. 16 MS. LOCKARD: Objection. It's vague. 17 BY MR. STANOCH: 18 Q. And that would include the identification, 19 characterization, testing, and control of any 20 potential genotoxic impurities, correct? 21 MS. LOCKARD: Objection. Compound. 22 Vague. Outside the scope of the class-certification 23 expert report. 24 THE WITNESS: Well, remember, ZHP and Teva 25 are working according to FDA requirements that speak</p>
<p style="text-align: right;">Page 39</p> <p>1 Q. Go ahead, Mr. Williams. 2 A. What I would say, Mr. Stanoch, is, you 3 know, the ANDA applicant has a responsibility to 4 look at the impurities in their drug substance and 5 their drug product and decide whether they need to 6 be reported, identified, and qualified. And those 7 are general recommendations that appear in the 8 guidances I cited. 9 It was only until 2015 that FDA produced 10 the guidance on how to deal with genotoxic 11 impurities, and that, of course, came to a head 12 three years later with the finding of the 13 nitrosamine impurities. 14 So I really can't answer your question 15 about the responsibility of a drug-product 16 manufacturer other than to refer you to that 2015 17 guidance. 18 Q. You are saying there was no guidance to 19 the drug industry about genotoxic impurities until 20 2015? 21 A. No, I think there were guidances, which I 22 allude to in my report. But the M7 guidance that 23 we're talking about now I think clarified it in 24 terms of how manufacturers need to focus on the 25 possibility of genotoxic impurities.</p>	<p style="text-align: right;">Page 41</p> <p>1 to identity, strength, quality, purity, and potency. 2 When we talk about purity, we're talking about 3 impurities. 4 And the guidances that ZHP and Teva would 5 use are the ones I cited in my report, both the ICH 6 Q3A and Q3B with revisions, and then also the 7 corresponding ANDA guidances. None of those 8 guidances mention genotoxic impurities. 9 BY MR. STANOCH: 10 Q. Are you saying, then, that Teva had no 11 obligation to potentially identify genotoxic 12 impurities in its finished-dose valsartan products? 13 MS. LOCKARD: Objection. Vague. Outside 14 the scope of class-certification expert report. 15 THE WITNESS: You know, I think it's clear 16 in my report that FDA gives recommendations in these 17 guidances, and that is what Teva and ZHP would be 18 following to submit their ANDA to FDA for review and 19 approval. 20 Now, if FDA had some concern about 21 genotoxic impurities based on the route of synthesis 22 of the drug substance, they could certainly bring 23 that to Teva's attention or the DMF-holder's 24 attention, in this case, ZHP. 25 But again, to talk about it generally in</p>

<p style="text-align: right;">Page 42</p> <p>1 terms of responsibility and liability is not 2 something I dealt with in my report. 3 BY MR. STANOCH: 4 Q. Uh-huh. So you are not offering any 5 opinion at this time about which firm would be 6 responsible for the identification of genotoxic 7 impurities in Teva's finished-dose valsartan 8 product? 9 A. I think if there was some reason to 10 suspect the presence of a genotoxic impurity, any 11 drug manufacturer would have to consider that and 12 discuss it with FDA in terms of what to do, but that 13 was not the case here. 14 Q. Uh-huh. Would it be your expectation that 15 Teva would have had systems in place to assure that 16 ZHP would promptly notify it in the event ZHP 17 identified a potential genotoxic impurity in 18 valsartan API? 19 MS. LOCKARD: Objection. Vague. Outside 20 the scope of the class-certification expert report. 21 THE WITNESS: You know, again, you are 22 asking these very general questions, but I would say 23 both ZHP and Teva are sort of marching, if you will, 24 to laws, regulations and guidances that come from 25 FDA, and for the most part those guidances don't</p>	<p style="text-align: right;">Page 44</p> <p>1 Q. Right. And the paragraph number there is 2 116. Do you see that? 3 A. I do. I do see that. Thank you. 4 Q. Right. Sure. 5 A. And your question about that is? I'm 6 sorry. 7 Q. Yeah, we will get back to that. Let's do 8 this housekeeping. So we scroll back up, that's 9 actually some misnumbering issue. You have another 10 Paragraph 116 starting under "Dr. Najafi's 11 Declaration" on page 38, right? 12 A. Yes, I apologize for these errors. I'm 13 sorry. 14 But I'm sure we can find the part of the 15 report that you want me to talk about. 16 Q. Sure. 17 A. So -- 18 Q. Well, hold on. Hold on. Sure. We could 19 fix. And just to button this up, so then it looks 20 like your paragraph numbering restarts, for the 21 record, on page 44, under the "Rebuttal to 22 Mr. Quick's Expert Declaration." Do you see that? 23 A. Yes, I do. It jumps from 127 and then to 24 110. 25 Q. Right.</p>
<p style="text-align: right;">Page 43</p> <p>1 speak to genotoxic impurities. 2 So if you are talking about a general 3 moral obligation, I could only answer in a personal 4 opinion, but I'm really trying to focus on the 5 regulatory requirements for an ANDA to be considered 6 and, if possible, approved. 7 BY MR. STANOCH: 8 Q. Well, Doctor, you are opining on whether 9 or not Teva followed GMP or proper regulatory 10 practice, I'm looking at Paragraph 116, right? 11 A. 116 speaks to Dr. Najafi's report. Is 12 that where we're looking, Mr. Stanoch? 13 Q. Oh. Well, that might be a separate issue, 14 Doctor. You know, your January 12th report, the 15 numbering -- there is two Paragraph 116s. It went 16 from 116 to 127, and then it restarted at 110. I 17 was looking at your conclusion. Maybe you fixed 18 that in your latest report. Let's take a look. 19 A. I'm sorry for those typo errors. 20 Can you point me exactly to where you are 21 looking, then? Is there a page number? 22 Q. I am looking at page 46, Doctor. 23 A. Okay. Good. 24 Q. And you see the heading "Conclusion"? 25 A. Yes, I do.</p>	<p style="text-align: right;">Page 45</p> <p>1 A. So I think to make sure we're always 2 talking about the right thing, I think if we just 3 give the paragraph number and the page, we should be 4 fine. Would that be all right with you, 5 Mr. Stanoch? 6 Q. Absolutely fine. And, Doctor, was there 7 some cutting-and-pasting issue with the section on 8 your rebuttal to Mr. Quick that messed up your 9 numbering of your paragraphs here? 10 A. No, I would say it was a word-processing 11 error, where you have to sort of back up and make 12 sure that the Word program numbers the paragraph 13 correctly. 14 Q. Sure. I have been there, Doctor. I'm 15 sure we all have. 16 No, did you write this whole section, the 17 "Rebuttal to Mr. Quick's Expert Declaration" in your 18 report? 19 A. I would say, you know, I wrote the report, 20 and I apologize for the limits on my word-processing 21 skills. 22 I did try to correct this. I think we 23 noticed some of the misnumbering when we were 24 looking at drafts, and apparently I failed to do it 25 in the final document.</p>

<p style="text-align: right;">Page 46</p> <p>1 Q. Again, that's totally understandable. I 2 was just getting at -- to say if you wrote this 3 section here, "Rebuttal to Mr. Quick's Expert 4 Declaration," or not? 5 A. Yes, I did. 6 Q. Uh-huh. And no one gave you that to cut 7 and paste into the report and that messed up your 8 numbering? 9 A. No. 10 Q. Uh-huh. You said "we" noticed some 11 pagination errors before. Who is the "we" in your 12 answer a couple answers ago? 13 A. Well, first of all, it's not a pagination 14 error, it's a paragraph-numbering error. I can tell 15 you exactly how it happens. But I think when we 16 were looking at drafts, one of the counsel pointed 17 out that the numbering was not consistent. 18 Q. Okay. Moving on, I'm looking at page 46, 19 your "Conclusions," Doctor. Tell me when you are 20 there. 21 A. Okay, Mr. Stanoch, I'm there. 22 Q. And the Paragraph 116 on this page, you 23 write in part, "Teva did not fail to follow cGMP or 24 proper regulatory practice." Do you see that? 25 A. I do.</p>	<p style="text-align: right;">Page 48</p> <p>1 learning from ZHP about the NDMA in valsartan API? 2 A. You know, you are asking a question that 3 sort of asks me to take your word for it. I don't 4 think I commented on when ZHP or FDA actually 5 informed Teva, but it was certainly in the May, 6 June, July time frame, and I think Teva acted 7 promptly to recall two of its ANDA valsartan 8 products from the U.S. market. 9 And that's the way the system is supposed 10 to work. That's what recalls do. It allows the 11 removal of a product that, for one reason or 12 another, needs to be removed from the market, either 13 because it fails GMPs or it fails a specification. 14 What is unusual, and I noted this in my 15 report, is the recall occurred before FDA had set a 16 limit on the nitrosamine impurity. So Teva was 17 acting, and I'm going to use FDA words, with what I 18 might call an abundance of caution to remove the two 19 valsartan products manufactured in Malta from the 20 U.S. market. 21 Q. Uh-huh. So what I hear you saying is the 22 system worked as it should here. 23 ZHP discovered NDMA in valsartan API 24 sometime in the summer of 2018 or shortly before, 25 right?</p>
<p style="text-align: right;">Page 47</p> <p>1 Q. Right. So you are opining on whether or 2 not Teva followed cGMP and proper regulatory 3 practice, right? 4 A. Yes. 5 Q. Right. So in the context of your opinions 6 on cGMP and proper regulatory practice, my question, 7 now several questions ago is: Do you believe that 8 Teva was following proper regulatory practice in 9 terms of its relationship with ZHP to ensure that it 10 was promptly notified about potential genotoxic 11 impurities in valsartan API? 12 A. I think the answer is yes. I think ZHP 13 was communicating to Princeton, they were 14 communicating with FDA, FDA was communicating with 15 Teva. And Teva promptly recalled all these 16 products, as my report says. So to me, that's the 17 way the system should work. 18 And Teva never was under any particular 19 GMP failure notice from FDA. I think FDA was 20 pleased with the way Teva worked out its recalls in 21 order to protect the public when they found out 22 about the nitrosamine impurities. I don't see a 23 failure, Mr. Stanoch. I see success. 24 Q. So you are saying, Doctor, that Teva acted 25 reasonably promptly in the summer of 2018 upon</p>	<p style="text-align: right;">Page 49</p> <p>1 A. Yes, I think you are saying it correctly, 2 Mr. Stanoch. 3 Q. ZHP told Teva, correct? 4 A. Well, again, I'm not sure of the routes of 5 communication. I think Princeton told FDA and FDA 6 told Teva, and pretty soon everybody is talking 7 about this difficult situation. 8 Q. Well, that's fine, whatever your 9 understanding of the route is. So ZHP told its 10 affiliate company, Princeton, right? 11 A. If you want to postulate the route of 12 communication, that's fine with me, Mr. Stanoch. 13 Q. No, I'm not postulating anything, Doctor. 14 I'm just trying to -- whatever your understanding 15 is, I'm not bickering with it. I'm just trying to 16 make sure I establish what you think the route is, 17 right? So ZHP, we already determined, identified 18 NDMA in valsartan API in 2018, right? We agree with 19 that? 20 A. And that information came to Princeton and 21 Princeton brought it to FDA, and then FDA started 22 looking at all the manufacturers of valsartan, and 23 there were several, who used the ZHP product. And 24 that included Teva for two of its four ANDAs. 25 Q. So how did the information about the NDMA</p>

<p style="text-align: right;">Page 50</p> <p>1 in 2018 get to Teva?</p> <p>2 A. I would be speculating, but to me, it</p> <p>3 might have come from FDA.</p> <p>4 Q. Well, whatever you think your answer is.</p> <p>5 I'm just trying to see what the telephone route of</p> <p>6 communication is.</p> <p>7 And that's what you were referring to more</p> <p>8 generally as the system working, that the API</p> <p>9 manufacturer passed the information along, and it</p> <p>10 went to the FDA and at some point it got to Teva,</p> <p>11 and then Teva, as you said, instituted its recalls</p> <p>12 for its product that contained the valsartan API,</p> <p>13 right?</p> <p>14 MS. LOCKARD: Objection. Vague.</p> <p>15 Compound. And outside of the scope to the extent</p> <p>16 this line of questioning is asking about what ZHP</p> <p>17 did or should have done.</p> <p>18 THE WITNESS: Yeah, I don't want to get</p> <p>19 into the details of the way you described the routes</p> <p>20 of communication, but I can certainly say that when</p> <p>21 these things come up, everybody needs to talk to</p> <p>22 everybody, including FDA, and FDA is the one that</p> <p>23 prompted Teva to make the recalls.</p> <p>24 BY MR. STANOCH:</p> <p>25 Q. Yeah, right. You opine that FDA asked</p>	<p style="text-align: right;">Page 52</p> <p>1 a page number. But yes, your Exhibit 1, page 36,</p> <p>2 Paragraph 109. It begins, "Somewhat unusual,"</p> <p>3 right?</p> <p>4 A. Yes. Yes. We are in the same place,</p> <p>5 Mr. Stanoch.</p> <p>6 Q. Perfect. And you wrote, "the FDA asked</p> <p>7 for recalls of drug products"; do you see that?</p> <p>8 A. Yes. I do see that. And I think that</p> <p>9 corresponds with what I said previously.</p> <p>10 Q. Right, right, right. Well, you were</p> <p>11 saying that FDA and Teva were talking previously,</p> <p>12 but you write in your report that FDA asked for the</p> <p>13 recalls, right?</p> <p>14 A. Well, FDA works with the manufacturer to</p> <p>15 make a voluntary recall. I would say the decision</p> <p>16 on the recall is up to the manufacturer.</p> <p>17 Q. Well, that's not what you wrote here in</p> <p>18 Paragraph 109, is it?</p> <p>19 A. You know, I think the way it works is FDA</p> <p>20 wishes a recall, and a manufacturer -- I don't think</p> <p>21 FDA has the authority to compel a recall. So the</p> <p>22 reason I say it's voluntary is it's up to Teva to</p> <p>23 say, yes, we will do this recall at your request,</p> <p>24 and that's what Teva did.</p> <p>25 I don't think we should quibble about, you</p>
<p style="text-align: right;">Page 51</p> <p>1 Teva to recall its valsartan containing the API from</p> <p>2 ZHP, right?</p> <p>3 A. Well, the recall was voluntary on Teva's</p> <p>4 part, but they certainly worked closely with FDA to</p> <p>5 make sure that FDA was satisfied with the way their</p> <p>6 recall occurred.</p> <p>7 Q. Uh-huh.</p> <p>8 A. And that recall was in, I want to say,</p> <p>9 June of 2018. Wait a minute. I may have the month</p> <p>10 wrong. I'm sorry, Mr. Stanoch. I can check that if</p> <p>11 you wish.</p> <p>12 Q. Well, I'm looking at Paragraph 109 of your</p> <p>13 report, Doctor. Tell me when you are there.</p> <p>14 A. All right. Which paragraph?</p> <p>15 Q. 109.</p> <p>16 A. And I see that on -- can you say the page,</p> <p>17 Mr. Stanoch?</p> <p>18 Q. 37, sir.</p> <p>19 MS. LOCKARD: It starts on 36.</p> <p>20 THE WITNESS: Okay, yes. I see that,</p> <p>21 Paragraph 109 on page 36.</p> <p>22 BY MR. STANOCH:</p> <p>23 Q. Stand by. Right. Yeah, you know, I have</p> <p>24 the earlier version of your report, not the one</p> <p>25 given to me this morning, so I'm sorry if I'm off by</p>	<p style="text-align: right;">Page 53</p> <p>1 know, who was actually driving the decision. I</p> <p>2 think it's a joint decision between FDA and Teva,</p> <p>3 but it's a voluntary act on the part of Teva.</p> <p>4 Q. Well, you know, Doctor, I can only ask</p> <p>5 questions about what you opine and write in your</p> <p>6 report, and what you wrote in your report twice in</p> <p>7 this paragraph is about the FDA asking for these</p> <p>8 recalls, correct?</p> <p>9 A. That could well be how a recall occurs,</p> <p>10 FDA finds something and they work with the company</p> <p>11 to execute a recall. But Teva was voluntarily</p> <p>12 making these recalls, and they did so successfully.</p> <p>13 And they kept FDA apprised of what they were doing,</p> <p>14 and FDA agreed with it.</p> <p>15 Q. Well, you don't write here in this</p> <p>16 paragraph or anywhere in your report that Teva went</p> <p>17 to the FDA and said, we're going to recall our</p> <p>18 product, did you?</p> <p>19 A. You know, I stand by the words in the</p> <p>20 document. Are you providing alternate words,</p> <p>21 Mr. Stanoch?</p> <p>22 Q. I'm not providing anything alternate,</p> <p>23 Dr. Williams. I'm focused on your words in</p> <p>24 Paragraph 109 of your report, where you twice say</p> <p>25 the FDA asked for the recalls.</p>

<p style="text-align: right;">Page 54</p> <p>1 A. Yes, I have no problem with FDA asking for 2 recalls. Does that seem a problem in terms of how 3 Teva executed the recall? 4 Q. I'm trying to establish based on your 5 words in your report, Doctor, that Teva did not go 6 to the FDA and said, we need to recall our product, 7 rather, the FDA asked Teva to recall the valsartan 8 product, correct? 9 A. I'm not going to debate the words with 10 you. I think you are right, Mr. Stanoch, that 11 Teva -- FDA was asking Teva and Teva responded to 12 this request. It was voluntary because I think Teva 13 could have said, no, we're not going to recall. 14 Teva did not do that. They voluntarily recalled. 15 But you are right, Teva initiated the 16 request based on their findings working with ZHP and 17 other manufacturers. 18 Q. I'm going to go back to sort of the chain 19 of communication about the NDMA discovery in June 20 2018. So do you think there was any direct 21 communication between ZHP and Teva about the NDMA 22 discovered in June 2018? 23 A. Well, I would have to speculate. It may 24 be in my materials considered, but I didn't cite 25 anything in that report, so at this point it would</p>	<p style="text-align: right;">Page 56</p> <p>1 part of my report. And I'm not a GMP expert, so I 2 very carefully combined my GMP opinions through 3 brief statements in this report. 4 BY MR. STANOCH: 5 Q. That's confusing to me, Doctor, because 6 the conclusion paragraph we were looking at is you 7 are opining that Teva did not fail to follow cGMP or 8 proper regulatory practice, right? 9 A. And I base that on my review of 10 inspections of Teva that occurred over the decade of 11 2010 to the present time. Teva did not have GMP 12 issues insofar as FDA was concerned, including GMP 13 issues related to the nitrosamine impurities. 14 Q. So the only basis for your opinion that 15 Teva did not fail to follow cGMP or proper 16 regulatory practice is the status of any FDA 17 inspections of Teva finished-dose facilities? 18 A. Yes, exactly. And that's where I spent 19 some time in my report, on that inspectional 20 history, and for the most part, I did not see any 21 particular GMP problems that FDA was bringing to 22 Teva's attention. 23 Q. So your opinions are not based in any way 24 on Teva's compliance with cGMP or proper regulatory 25 practice vis-à-vis its API suppliers ZHP and Mylan?</p>
<p style="text-align: right;">Page 55</p> <p>1 be speculative for me to answer. I would be very 2 surprised if ZHP and Teva weren't communicating on 3 this point. 4 Q. Okay. Would it be proper regulatory 5 practice for ZHP to be in communication with its 6 customer Teva about the discovery of NDMA in the 7 valsartan API? 8 MS. LOCKARD: Object to the extent you are 9 asking him about what ZHP should or shouldn't have 10 done. It's outside the report. 11 THE WITNESS: It seems to me, if a 12 drug-substance manufacturer finds an unidentified 13 impurity that is problematic in their drug 14 substance, they would certainly notify their 15 purchasers. 16 BY MR. STANOCH: 17 Q. What cGMP procedures did Teva have in 18 place to assure that ZHP would inform Teva about any 19 genotoxic impurities in APIs that Teva was 20 purchasing? 21 MS. LOCKARD: Objection. Vague. Scope. 22 THE WITNESS: You know, Mr. Stanoch, we 23 may look for it in my materials considered, but I 24 did not study that to form my opinions, and I don't 25 think I cite anything into that part of my -- any</p>	<p style="text-align: right;">Page 57</p> <p>1 MS. LOCKARD: Objection. Vague. 2 Confusing. 3 THE WITNESS: Yes, I did not explore 4 separate from FDA inspections how Teva's SOPs 5 conform to FDA's requirements on GMPs. That was not 6 part of my report. 7 BY MR. STANOCH: 8 Q. Okay. Well, why do you list all Teva's 9 SOPs in your reliance materials, then, Doctor? 10 A. There is a huge amount of material in my 11 materials-considered document, and I would say only 12 a small fraction of that was cited in my report, and 13 even that small fraction was voluminous. 14 Q. So am I to take it, then, that the 15 materials that you only relied on for your opinions 16 at this stage are the ones quoted in the -- or cited 17 in the body of your report, not all of them listed 18 in your reliance materials? 19 A. No, I think if it is cited in my report, 20 it should be listed in my materials-considered list. 21 Was that your question, Mr. Stanoch? 22 Q. No. My question is a little different, 23 Doctor. You know, you list a lot of stuff in your 24 reliance materials, including Teva's SOPs, but now 25 you are telling me your opinions don't turn on</p>

<p style="text-align: right;">Page 58</p> <p>1 Teva's SOPs as it relates to Teva's relationship 2 with its API suppliers, right? 3 MS. LOCKARD: Objection. Lacks 4 foundation. Vague. Misstates the document. 5 THE WITNESS: Yes, I think I make -- my 6 opinions are clearly stated both at the beginning 7 and at the end of the report and I provide citations 8 to support those opinions, but I certainly didn't 9 get into the adequacy of Teva's SOPs with regard to 10 conformance to FDA's GMPs. That would have been a 11 completely different report. 12 BY MR. STANOCH: 13 Q. So how am I to know from your reliance 14 materials, Doctor, which materials you are relying 15 on, the opinions in the body of your report? 16 A. I think the best way I could answer that, 17 Mr. Stanoch, is to look at the citations in my 18 report, which are also listed in the materials 19 considered. 20 Q. Got it. So -- 21 MS. LOCKARD: Objection to that question 22 because you continue to name the list of materials 23 considered as his reliance materials, which is 24 confusing and vague and lacks foundation. 25</p>	<p style="text-align: right;">Page 60</p> <p>1 THE VIDEOGRAPHER: Okay. So we're going 2 off the record. The time is 8:42. 3 (Whereupon, a brief recess was taken.) 4 THE VIDEOGRAPHER: Okay. We're coming 5 back on the record. The time on the video monitor 6 is 8:51. Please begin. 7 BY MR. STANOCH: 8 Q. Doctor, just yes/no, did you talk to your 9 counsel during the break? 10 A. Yes, I did. 11 Q. Did you talk to anyone else? 12 A. No, not at all. 13 Q. Did you look at any documents? 14 A. Did we look at any documents? 15 Q. Correct. 16 A. I think there was one document we looked 17 at. 18 Q. What did you look at? 19 A. It was a management document of Teva that 20 went out globally to many scores of people about -- 21 and it's cited in my report -- about the problem 22 with the ZHP drug substance having nitrosamine 23 impurities. 24 Q. Where is that cited in your report? 25 THE WITNESS: Can you tell me where it is</p>
<p style="text-align: right;">Page 59</p> <p>1 BY MR. STANOCH: 2 Q. So let me make sure I fully understand it, 3 then. So the materials you rely upon to render your 4 opinions reflected in your report are the ones that 5 are cited in the body of the report? 6 A. Yes, I think as a general statement, 7 Mr. Stanoch, that's correct. And as you can see, 8 it's only a small fraction of all the materials 9 listed in the materials-considered document. 10 Q. Okay. So if an item is listed in your 11 materials considered but not cited in the body of 12 the report, you are not relying on that material in 13 rendering your opinions at this time? 14 A. I think I can agree with that. 15 Q. That's fine. It will make the day go 16 faster, Doctor. Again, I just want to make sure 17 we're on the same field. I appreciate that. 18 MS. LOCKARD: So I think we have been 19 going about an hour, if you are at a point in 20 time -- you are changing topics -- 21 MR. STANOCH: That's fine. Doctor, would 22 you like a break? 23 THE WITNESS: That would be very nice, 24 Mr. Stanoch. 25 MR. STANOCH: Let's do it.</p>	<p style="text-align: right;">Page 61</p> <p>1 in the cited materials? 2 Okay. It's on page 9, and it's Reference 3 9 on page 9, I believe. 4 BY MR. STANOCH: 5 Q. Is that "Notification Letter from 6 Valsartan re" -- sorry. Start over. "Notification 7 Letter from re Valsartan" "update"? 8 MS. LOCKARD: Just to clear it up, it's -- 9 sorry, you're not trying to -- I know you are just 10 trying to figure out which document it is. The 11 document is 565758. 12 THE WITNESS: Yes, and it's Reference 9. 13 There are actually two references in Reference 9, 14 and it's the first that we looked at briefly. 15 BY MR. STANOCH: 16 Q. Why don't you tell me the Bates numbers of 17 the two documents you looked at? 18 MS. LOCKARD: He looked at one document. 19 He is saying there are two documents referenced in 20 Footnote 9. 21 MR. STANOCH: Oh, I'm sorry, Counsel. I 22 thought he was looking at his materials considered. 23 We are looking at his footnote in his report. Thank 24 you. That's helpful. I see it now, thank you. 25 Q. Did that document refresh your</p>

<p style="text-align: right;">Page 62</p> <p>1 recollection about anything you had looked at 2 before?</p> <p>3 A. No. I don't think it's really pertinent 4 to the questioning. I'm glad to ask questions about 5 it if you wish, Mr. Stanoch.</p> <p>6 Q. Sure. I just need to get a copy of it and 7 to share it for all of our colleagues who are 8 remote, so give me one second. Okay. We will mark 9 that document as Williams Exhibit 3. 10 (Whereupon, Exhibit 3 was marked for 11 identification.)</p> <p>12 THE WITNESS: And if I -- Mr. Stanoch, may 13 I point out something in the document that was 14 helpful to some of your questions?</p> <p>15 BY MR. STANOCH:</p> <p>16 Q. Before you do that, let's make sure I have 17 the same document as you. I'm going to share my 18 screen, Doctor. You will see it looks like a -- 19 it's an e-mail from June 21, 2018, Bates No. 565758. 20 Is this the same document you are holding?</p> <p>21 A. Yes, I believe so.</p> <p>22 Q. Great. I'm going to stop sharing now that 23 we're on the same page.</p> <p>24 This is the document you were referring to 25 that you looked at, right?</p>	<p style="text-align: right;">Page 64</p> <p>1 break, FDA asked for the recall, but Teva 2 voluntarily did the recall, working with FDA and to 3 FDA's satisfaction.</p> <p>4 Q. You think it was appropriate for Teva to 5 wait, as you said, a month later after being told by 6 ZHP about the NDMA impurity, to institute its 7 recalls?</p> <p>8 MS. LOCKARD: Objection to the form of 9 that question. It lacks foundation and it misstates 10 the evidence.</p> <p>11 THE WITNESS: Well, you know, you can 12 imagine, I'm speaking generally, not to anything I 13 said in my report, but this is an incredibly 14 difficult finding, inspecting a company making 15 products all over the globe, including FDA. And of 16 course FDA is a very stringent regulatory authority, 17 so it doesn't surprise me at all that by the time 18 they sorted through the issues, it took about a 19 month to get the product off the U.S. market.</p> <p>20 BY MR. STANOCH:</p> <p>21 Q. Okay.</p> <p>22 A. And that's what my report says. And at no 23 time was Teva's product ever deemed adulterated or 24 misbranded, and it was always AB-rated. So I think 25 Teva acted with incredible swiftness.</p>
<p style="text-align: right;">Page 63</p> <p>1 A. Yes. And if you look at the four-digit 2 page number ending 5763 --</p> <p>3 Q. Okay.</p> <p>4 A. -- you can see at the top there is a 5 reference to when ZHP informed Teva that "they came 6 to be aware of a previously unknown impurity that 7 may have genotoxic potential," and that was on 8 June 20th, 2018.</p> <p>9 Q. Got it. And it's your opinion that Teva 10 acted appropriately, promptly, after receiving 11 notification from ZHP on June 20th, 2018?</p> <p>12 A. Yes. The way I would say it, if you look 13 further down, where it says "Investigation," "sites 14 to requested to remove any materials or products 15 using Valsartan API from Zhejiang" -- ZHP.</p> <p>16 So to me, you know, this is a very rapid 17 response on the part of Teva to a problem brought to 18 their attention by ZHP. Remember, the date of the 19 e-mail is 6/21 and they are notified by ZHP on 6/20, 20 so I don't think you could have a much more rapid 21 response.</p> <p>22 And then subsequently to this notice, Teva 23 also issued the recall. And I believe that was in 24 July 16th, 2018, so that was about a month later. 25 And again, as we discussed before the</p>	<p style="text-align: right;">Page 65</p> <p>1 And remember, the issue is not could the 2 nitrosamine impurity be there or not. It could be 3 there. It just didn't have a limit. And FDA set 4 that limit in December 2018.</p> <p>5 Q. Uh-huh. Well, nothing stopped Teva from 6 taking its valsartan with ZHP API in it off the 7 market sooner than when the FDA asked, right?</p> <p>8 MS. LOCKARD: Objection. Vague.</p> <p>9 THE WITNESS: No, I think you're asking 10 for sort of a personal opinion. It seemed to me it 11 happened remarkably quickly, Mr. Stanoch. It wasn't 12 anything that was delayed.</p> <p>13 You know, to issue a recall and discuss 14 with the FDA how to do the recall takes some time. 15 So if you ask me, a few weeks, was that unusual, I 16 don't think it was unusual at all.</p> <p>17 BY MR. STANOCH:</p> <p>18 Q. Uh-huh. It's your opinion that this is 19 how it's supposed to happen, right? ZHP became 20 aware of the impurity, looks like they told Teva, 21 and then Teva acted, based on this Exhibit 3, right?</p> <p>22 MS. LOCKARD: Objection. Vague.</p> <p>23 THE WITNESS: Again, it -- I think I'm 24 speaking personally, but I think Teva's activities 25 here were highly responsible and laudatory.</p>

<p style="text-align: right;">Page 66</p> <p>1 BY MR. STANOCH:</p> <p>2 Q. Okay. And would you say that this is an</p> <p>3 example of -- in your words from prior to the</p> <p>4 break -- as how the system is supposed to work in</p> <p>5 terms of notification about the impurity with</p> <p>6 genotoxic potential finding its way back to Teva?</p> <p>7 A. Yes, I appreciate those words,</p> <p>8 Mr. Stanoch. Thank you.</p> <p>9 Q. And you would expect this to be the case</p> <p>10 of how it should work for the discovery of genotoxic</p> <p>11 impurities in API that a manufacturer like Teva is</p> <p>12 buying generally, right?</p> <p>13 A. Well, that's a very general statement.</p> <p>14 But I think in terms of the specifics here with a</p> <p>15 very difficult impurity to identify and measure,</p> <p>16 which can be there, it just needs a limit, Teva did</p> <p>17 something quite remarkable. They might --</p> <p>18 Q. If -- I'm sorry. Go ahead.</p> <p>19 A. I'm speculating, but they might have said</p> <p>20 to FDA, well, let's wait until we figure out what</p> <p>21 the limit should be, and, you know, they may not</p> <p>22 have needed to do a recall at all. But they acted</p> <p>23 highly responsibly at FDA's request.</p> <p>24 Q. Uh-huh. Right. If ZHP came to be aware</p> <p>25 of a genotoxic impurity earlier than 2018, would you</p>	<p style="text-align: right;">Page 68</p> <p>1 from the equation is the limits that FDA set in</p> <p>2 December 2018.</p> <p>3 BY MR. STANOCH:</p> <p>4 Q. Were there any acceptable limits for</p> <p>5 nitrosamines in valsartan API as of June 20, 2018?</p> <p>6 A. Not that I'm aware of, no.</p> <p>7 Q. Uh-huh. Right. Nitrosamines were --</p> <p>8 there was -- strike that.</p> <p>9 Right. There was no established</p> <p>10 acceptable limit for nitrosamines in any valsartan</p> <p>11 products prior to June 2018, correct?</p> <p>12 A. Or any chemically synthesized drug in the</p> <p>13 U.S. market.</p> <p>14 Q. Right. Because no one expected the</p> <p>15 nitrosamines to be in them, correct?</p> <p>16 A. You are reiterating what FDA said. This</p> <p>17 was unexpected.</p> <p>18 Q. Well, unexpected, you say that numerous</p> <p>19 times in your report, Doctor. We will get back to</p> <p>20 that.</p> <p>21 But is it your opinion that without the</p> <p>22 interim guidelines, there were no guidances out</p> <p>23 there which would have indicated what level of</p> <p>24 nitrosamines were allowable in valsartan API or</p> <p>25 finished dose?</p>
<p style="text-align: right;">Page 67</p> <p>1 expect ZHP to inform Teva of that?</p> <p>2 MS. LOCKARD: Objection. Outside the</p> <p>3 scope of his opinions. He is not here to give</p> <p>4 liability opinions about ZHP.</p> <p>5 THE WITNESS: Yes, and I don't have any</p> <p>6 information on that, Mr. Stanoch, and I don't</p> <p>7 believe I cited anything about that question.</p> <p>8 BY MR. STANOCH:</p> <p>9 Q. In your answer a moment ago, you said Teva</p> <p>10 did something quite remarkable. Is it your opinion</p> <p>11 that Teva should have allowed their valsartan to be</p> <p>12 sold on the market while the FDA came up with</p> <p>13 interim limits?</p> <p>14 A. I think that's a possible conjecture.</p> <p>15 Q. So you are saying Teva could have --</p> <p>16 strike that.</p> <p>17 So you are saying Teva could have kept</p> <p>18 selling its valsartan with the NDMA in it until the</p> <p>19 FDA came up with interim limits?</p> <p>20 MS. LOCKARD: Objection. Vague.</p> <p>21 Speculation.</p> <p>22 THE WITNESS: Yeah, I am speculating, but</p> <p>23 I point out that it was unusual for FDA to ask a</p> <p>24 recall of an impurity which FDA says can be in a</p> <p>25 drug product and a drug substance. What was missing</p>	<p style="text-align: right;">Page 69</p> <p>1 A. That's my understanding.</p> <p>2 Q. Right. So until the FDA caught ZHP, it</p> <p>3 was okay for any amount of nitrosamines to be in</p> <p>4 valsartan API; is that what you are saying?</p> <p>5 MS. LOCKARD: Objection to the form of the</p> <p>6 question. Argumentative.</p> <p>7 THE WITNESS: Yeah, no, I'm not saying</p> <p>8 that at all, but of course, you are dealing with an</p> <p>9 impurity which has a presence in food, and sometimes</p> <p>10 quite high levels. So FDA had just never crossed</p> <p>11 this bridge, nor had U.S. industry. Now, as a</p> <p>12 result of the events of the summer of 2018, they</p> <p>13 have crossed the bridge, so things are better.</p> <p>14 BY MR. STANOCH:</p> <p>15 Q. So you are saying until the FDA</p> <p>16 established acceptable intake limits for</p> <p>17 nitrosamines, it was okay whatever limit -- strike</p> <p>18 that.</p> <p>19 You are saying that valsartan API could</p> <p>20 have nitrosamines in it until the FDA established</p> <p>21 interim acceptable limits?</p> <p>22 A. Well, that's true now. You can have --</p> <p>23 FDA will allow nitrosamine in drug products as long</p> <p>24 as they are within the acceptable intake limits.</p> <p>25 FDA is not saying that a product needs to have no</p>

<p style="text-align: right;">Page 70</p> <p>1 nitrosamine impurities. That is not true.</p> <p>2 Q. So it's your opinion that a drug</p> <p>3 manufacturer could have had any amount of</p> <p>4 nitrosamines in their drugs prior to the interim</p> <p>5 limits and that did not pose any concern?</p> <p>6 A. I don't believe I said that anywhere in my</p> <p>7 report, but if you can point it out, Mr. Stanoch, I</p> <p>8 would be glad to comment.</p> <p>9 Q. Well, I'm asking you now if that's your</p> <p>10 opinion, Doctor.</p> <p>11 A. You want me to add that to my opinion in</p> <p>12 my report?</p> <p>13 Q. Are you of the view that prior to the</p> <p>14 FDA's establishment of acceptable intake limits for</p> <p>15 nitrosamines, there was no prohibition on the amount</p> <p>16 of nitrosamines that could be in a drug product?</p> <p>17 A. I think you are saying that correctly,</p> <p>18 because FDA didn't know how to measure for it,</p> <p>19 neither did industry. That all had to be worked</p> <p>20 out. And then once you could measure it, then you</p> <p>21 could begin, you know, following the recommendations</p> <p>22 of the 2015 guidance. And FDA did all that and came</p> <p>23 to a limit.</p> <p>24 Now, you are sort of asking the question:</p> <p>25 What happens before you do all that work? And I</p>	<p style="text-align: right;">Page 72</p> <p>1 Q. Uh-huh.</p> <p>2 A. Time marches on, regulation marches on.</p> <p>3 If you want to go back in the past and say</p> <p>4 everything was awful or not as good as it is now, I</p> <p>5 don't want to say that.</p> <p>6 Q. Well, respectfully, Dr. Williams, things</p> <p>7 in the past were awful for some of the plaintiffs</p> <p>8 who got these drugs with a genotoxic carcinogen in</p> <p>9 it. So we are talking about that today, all right?</p> <p>10 Do you understand that?</p> <p>11 MS. LOCKARD: I'm going to object to that.</p> <p>12 That's not a question --</p> <p>13 MR. STANOCH: Withdrawn. I will withdraw</p> <p>14 it.</p> <p>15 Q. You understand this case is about in part</p> <p>16 folks who took the drug, and they had nitrosamines</p> <p>17 in it, right?</p> <p>18 A. I do understand that, and I would be loath</p> <p>19 to have an opinion about whether or how people were</p> <p>20 damaged by the presence of those nitrosamines. I'm</p> <p>21 not offering a toxicology or pharmacology opinion.</p> <p>22 Q. Right. And it's your opinion, though,</p> <p>23 that until the FDA established the acceptable intake</p> <p>24 limits -- and when was that? The final guidance</p> <p>25 was, what, February 2021, I believe you say?</p>
<p style="text-align: right;">Page 71</p> <p>1 guess the answer is, you know, that's how science</p> <p>2 progresses, that's how regulation progresses, and</p> <p>3 we're all the better for it now. I really can't</p> <p>4 speak to the past.</p> <p>5 Q. Well, isn't it incumbent on a drug</p> <p>6 manufacturer to identify potential genotoxic</p> <p>7 impurities in its product?</p> <p>8 A. You know, Mr. Stanoch, you keep asking</p> <p>9 these questions that are very general. Let me point</p> <p>10 out -- I don't know if you consider this germane,</p> <p>11 but let me say in the 1980s, before there was</p> <p>12 analytical technology, there were a whole bunch of</p> <p>13 impurities that neither FDA nor industry could even</p> <p>14 measure. What do you say about that?</p> <p>15 I mean, are drugs more pure now, better</p> <p>16 controlled than they were in the 1980s? And my</p> <p>17 answer to that is yes. No question about it. You</p> <p>18 know, ICH and FDA worked together to bring that</p> <p>19 better control for what I will call usual impurities</p> <p>20 through the ICH documents.</p> <p>21 And then later on, now, FDA came out with</p> <p>22 the guidance in 2015 that extended it to genotoxic</p> <p>23 impurities. And then the nitrosamine brought it all</p> <p>24 to the fore for a particular genotoxic impurity. So</p> <p>25 we're better off now.</p>	<p style="text-align: right;">Page 73</p> <p>1 A. No, but there were interim limits</p> <p>2 established in December 2018, and those carried</p> <p>3 forward into the guidance that appeared in</p> <p>4 September 2020, with an update in February 2021.</p> <p>5 Q. Uh-huh. So it's your opinion that prior</p> <p>6 to December 2018, a drug can have any amount of NDMA</p> <p>7 in it with no regulatory consequence?</p> <p>8 A. I wouldn't offer that opinion. I think it</p> <p>9 seems like a dangerous opinion to offer, and I'm</p> <p>10 surprised you state it.</p> <p>11 Q. If a drug had 1,000 nanograms of NDMA in</p> <p>12 it in January of 2018, would that be appropriate?</p> <p>13 MS. LOCKARD: Objection. Vague.</p> <p>14 THE WITNESS: You know, I just can't</p> <p>15 comment on those kind of questions. You are getting</p> <p>16 into how does the FDA set limits for certain</p> <p>17 impurities. And, you know, it has to be done</p> <p>18 carefully and in the context of background, food</p> <p>19 impurities that are nitrosamine impurities. I just</p> <p>20 can't answer that question, Mr. Stanoch.</p> <p>21 BY MR. STANOCH:</p> <p>22 Q. Uh-huh. So you see no problem with a drug</p> <p>23 product that had a thousand nanograms of NDMA in it</p> <p>24 in January 2018?</p> <p>25 A. I didn't offer that opinion.</p>

<p style="text-align: right;">Page 74</p> <p>1 Q. I'm asking you, do you see any issue with 2 a drug having a thousand nanograms of NDMA in it in 3 January 2018? 4 MS. LOCKARD: Objection. Vague. Outside 5 the scope of his class-certification report. 6 THE WITNESS: You know, and some of it, as 7 you well know, Mr. Stanoch, relates to the amount of 8 drug in the drug product and the duration of dosing. 9 I mean, your hypothesis might be okay for a drug 10 that's just taken once and never taken again as a 11 single oral tablet. 12 BY MR. STANOCH: 13 Q. Uh-huh. 14 A. I just can't answer your question. There 15 are too many factors that you are not specifying. 16 Q. Uh-huh. Uh-huh. So you can't tell me 17 whether it was okay for any valsartan drug to have 18 NDMA in it prior to the interim limits of 19 December 2018? 20 MS. LOCKARD: Objection. Vague. 21 THE WITNESS: No, I do know that. FDA has 22 said you could have nitrosamine in your drug 23 product. They say that even now. The question is: 24 What are the limits? And, you know, you can read 25 about it in the guidance in terms of daily dose and</p>	<p style="text-align: right;">Page 76</p> <p>1 THE WITNESS: Yes, I think that's what FDA 2 would say. And remember, there can be many 3 impurities in a drug substance that are below 4 detectable limit that you just never know about. I 5 mean, we're getting into hypotheticals that are 6 beyond my report. 7 BY MR. STANOCH: 8 Q. Is it your opinion, sir, that without the 9 interim guidelines, there were no guidances 10 available which would have indicated what levels of 11 nitrosamines could be present in valsartan? 12 MS. LOCKARD: Objection. Asked and 13 answered. 14 THE WITNESS: Yes, that's my 15 understanding, that those limits came in 16 December 2018 from FDA. 17 BY MR. STANOCH: 18 Q. Uh-huh. So prior to December 2018, there 19 was no guidance available to the industry about 20 levels of nitrosamines in valsartan? 21 MS. LOCKARD: Objection. Asked and 22 answered. 23 THE WITNESS: Yes, I -- do you want me to 24 repeat my answer, Mr. Stanoch? 25</p>
<p style="text-align: right;">Page 75</p> <p>1 duration of dose. That's how they come to these 2 limits. 3 BY MR. STANOCH: 4 Q. Do you agree that there was no acceptable 5 limit for nitrosamines prior to December 2018? 6 A. That's my understanding. The FDA did not 7 have limits for the nitrosamine impurities before 8 December 2018. 9 Q. So without an acceptable limit, then the 10 limit is zero, isn't it? 11 A. No. No, no. I wouldn't say that at all. 12 I don't know how you come to zero. 13 Q. Uh-huh. Well, the purpose of a limit is 14 to say you can have this much of a substance in the 15 drug, right? 16 A. Up to the limit. 17 Q. Correct. Up to the limit. Right. And so 18 until that limit was determined, you can't have more 19 than zero amount of a substance in it, can you? 20 A. No, no, I wouldn't agree with that at all. 21 Q. Well, so even without an interim limit, 22 you are saying it was appropriate for a drug to have 23 some amount of nitrosamine in it? 24 MS. LOCKARD: Objection. Asked and 25 answered.</p>	<p style="text-align: right;">Page 77</p> <p>1 BY MR. STANOCH: 2 Q. Please answer the question. 3 A. No, my understanding is I don't think 4 there were specified limits for any nitrosamine 5 impurity before December 2018. 6 Q. So I'm trying to understand your opinions, 7 Doctor. So if there is not an established limit for 8 a certain substance in a drug, then you can have 9 that substance in the drug? 10 MS. LOCKARD: Objection. Vague. Also 11 outside the scope of his expert report for class 12 certification. 13 THE WITNESS: Yes, and I'm looking at my 14 opinion where -- if we go to Page 46, where I look 15 at my conclusions, I don't think I speak to the 16 limit in that set of conclusions. But if you think 17 I did, please draw my attention to it, Mr. Stanoch. 18 BY MR. STANOCH: 19 Q. Doctor, you reference interim limits 20 throughout your report, don't you? 21 A. As provided by FDA in December 2018. I 22 don't speak to them in any other context, just 23 something that came from FDA. 24 Q. Uh-huh. So if there is not an established 25 limit for a certain substance in a drug, you are</p>

<p style="text-align: right;">Page 78</p> <p>1 saying that substance can be in the drug, no 2 problem? 3 MS. LOCKARD: Objection. Vague. Asked 4 and answered. Outside the scope of the 5 class-certification expert report. 6 THE WITNESS: And that really isn't what 7 I'm saying. I would say if somebody found a 8 nitrosamine impurity in their drug product in 2018, 9 they would properly follow the 2015 guidance and try 10 to figure out a limit. But as I point out in my 11 report, FDA did that for the entire industry. They 12 didn't wait for a single manufacturer to do it. 13 BY MR. STANOCH: 14 Q. Uh-huh. If a manufacturer found a 15 nitrosamine impurity in their drug product in 2018, 16 they should have properly followed the 2015 guidance 17 to try to figure out a limit, correct? 18 A. I think you are saying it correctly. I'll 19 give a little bit more specification to your 20 example. Let's say an NDA applicant who is building 21 an application for consideration by FDA, if they 22 found a nitrosamine impurity, they could follow the 23 2015 guidance and figure out a limit for it and then 24 submit that to FDA, and FDA would review it and say, 25 yeah, that limit is okay, or, no, we want you to do</p>	<p style="text-align: right;">Page 80</p> <p>1 I'm speculating, that before FDA set limits, an 2 individual company could have done it, and that 3 might have been perfectly okay. 4 And even now, I suppose -- company or a 5 consortium of company could try to convince FDA to 6 set higher limits than the ones they set in 7 December 2018. It's all subject to good data and a 8 good scientific review. 9 BY MR. STANOCH: 10 Q. Uh-huh. 11 A. So I'm not debating what you are saying at 12 all, Mr. Stanoch. 13 Q. Good. And I think we can agree, then, 14 that under the ICH M7(R1) guidance from 2015, it 15 would be incumbent on the manufacturer that 16 discovered a genotoxic impurity to attempt to 17 characterize, test it and potentially set limits on 18 its own without regulatory action, correct? 19 MS. LOCKARD: Objection. Outside the 20 scope. 21 THE WITNESS: Well, I would agree with 22 your statement, except without regulatory action, 23 because whatever the company would do would be 24 subject to FDA review and approval. 25</p>
<p style="text-align: right;">Page 79</p> <p>1 something different. 2 But in this case, FDA did that work for 3 industry. So I would say industry now doesn't need 4 to figure out their own limits. FDA has done that 5 for them. And that's what is described in the 6 guidance that I cite. 7 Q. Uh-huh. And you referenced a 2015 8 guidance. What are you talking about? 9 A. I think that's the M7 guidance. 10 Q. That's the ICH M7(R1) guidance, correct? 11 A. Yes. And I think I do cite that, so it 12 should be in my materials considered. 13 Q. No, you do. I'm not -- issuing with that. 14 I want to make sure I understood what you meant by 15 2015 guidance in your answer. 16 So I understand you are saying the FDA 17 here set limits eventually for nitrosamines. But if 18 a manufacturer had reason to believe its product 19 contained nitrosamines, the appropriate course would 20 have been for them to work towards establishing 21 limits on their own prior to any FDA guidance, 22 correct? 23 MS. LOCKARD: Objection. Outside the 24 scope of his class-certification expert opinions. 25 THE WITNESS: Yes, I could imagine, and</p>	<p style="text-align: right;">Page 81</p> <p>1 BY MR. STANOCH: 2 Q. Fair enough. So then, I guess, to clarify 3 it, we agree, then, that under the ICH M7(R1) 4 guidance from 2015, it would be incumbent on the 5 manufacturer that suspected genotoxic impurity to 6 attempt to characterize it, test it, and potentially 7 set limits for it, and letting the regulatory body 8 know? 9 A. And letting the regulatory body see the 10 data and review it and approve it. 11 Q. That's fair. Let's take that same 12 situation and say we're talking about an API 13 manufacturer first, okay? You with me? 14 A. Okay. 15 Q. Okay. Right. Would you agree that under 16 the ICH M7(R1) guidance from 2015, it would be 17 incumbent on an API manufacturer that suspected a 18 genotoxic impurity to attempt to characterize it, 19 test it and potentially set limits for it, not only 20 in connection with the regulatory body, but also 21 customers purchasing that API? 22 MS. LOCKARD: Objection. This is getting 23 far outside the scope of his class-certification 24 expert report, Counsel. You are asking him about 25 API manufacturers and their requirements. That's a</p>

<p style="text-align: right;">Page 82</p> <p>1 liability opinion. He hasn't been retained for that 2 issue, and specifically not for ZHP or any API 3 manufacturers. 4 THE WITNESS: You know, and I would add, 5 Mr. Stanoch, that if we're going to talk about it, 6 it might be good to put that guidance on the screen 7 and see exactly who it's directed to. Usually, when 8 FDA creates a guidance with recommendations, they 9 identify who it's intended for. And I'll be glad to 10 review that with you if we could sort of find it. 11 It did not figure prominently in my report 12 or my opinions because, as I have already noted, FDA 13 did this for industry. I didn't have to look at 14 what an industry drug-substance or drug-product 15 manufacturer would have or should have done. 16 BY MR. STANOCH: 17 Q. We can look at the ICH guidance in a 18 little bit, but sitting here right now, Doctor, is 19 it your view that the ICH M7(R1) guidance applies 20 only to finished-dose manufacturers, not API 21 manufacturers? 22 A. No, I wouldn't say that. And if I looked 23 at the nitrosamine guidance, I think when -- if we 24 put that up, I think FDA is speaking to 25 manufacturers of drug products and also drug</p>	<p style="text-align: right;">Page 84</p> <p>1 MR. STANOCH: Enough, Counsel. 2 THE WITNESS: I would say at this point in 3 time, Mr. Stanoch, I can't add anything more to what 4 I have already said. 5 But I'm not going to disagree with you 6 that, you know, a drug-substance manufacturer that 7 suspects a genotoxic impurity would want to follow 8 the guidance and, you know, make sure that it's a 9 selling point to customers that we're controlling 10 genotoxic impurities. That's a good drug substance. 11 BY MR. STANOCH: 12 Q. Uh-huh. Do you agree that nitrosamines 13 are probable human carcinogens? 14 MS. LOCKARD: Objection. Outside the 15 scope of his retention, his expert report, his 16 disclosure. 17 THE WITNESS: Yeah, I'm certainly not 18 offering opinion about that, but I have read the 19 statements in the materials cited and some of the 20 materials considered that would cause me to agree 21 with what you said, Mr. Stanoch. 22 BY MR. STANOCH: 23 Q. Do you agree that nitrosamines are 24 genotoxic? 25 A. Yeah, for purposes of discussions I will</p>
<p style="text-align: right;">Page 83</p> <p>1 substances. 2 Q. Uh-huh. All right. I'm going to repeat 3 my question a little bit ago because you didn't 4 answer it when you said you wanted to look at the 5 MCH guidance. 6 So would you agree that under the ICH 7 M7(R1) guidance from 2015, it would be incumbent on 8 an API manufacturer that suspected a genotoxic 9 impurity to attempt to characterize it, test it, 10 potentially set limits for it, and to let the 11 regulatory body and its API customers know? 12 MS. LOCKARD: I am going to object to this 13 question. He said he's not going to answer it. He 14 wants to look at the document. So you are asking 15 him to interpret a document and you are refusing to 16 provide it to him, so I have an objection. 17 We can take a break and get it if you want 18 him to interpret it. It's also outside the scope of 19 his expert opinion, however. 20 BY MR. STANOCH: 21 Q. Go ahead, Dr. Williams. 22 A. I'm sorry, Mr. Stanoch. 23 Q. Please answer the question. 24 MS. LOCKARD: If you can answer the 25 question.</p>	<p style="text-align: right;">Page 85</p> <p>1 agree with that, Mr. Stanoch. 2 Q. Do you agree that nitrosamines are not an 3 active ingredient in any FDA-approved drug? 4 MS. LOCKARD: Objection. Speculation. 5 THE WITNESS: To the best of my knowledge, 6 Mr. Stanoch, I can agree with that. 7 BY MR. STANOCH: 8 Q. Uh-huh. Do you agree that the presence of 9 nitrosamines even at trace level is considered 10 unacceptable because these impurities are probable 11 human carcinogens? 12 MS. LOCKARD: Objection. Outside the 13 scope of his retention and his expert report on 14 class certification. He is not here to testify 15 about whether the drug is a potential human 16 carcinogen. But if you want to waste your time 17 asking him causation questions, have at it. 18 MR. STANOCH: Counsel, I don't need the 19 colloquy. Thank you. 20 Please answer, Dr. Williams. 21 THE WITNESS: Would you restate the 22 question, Mr. Stanoch? I'm sorry. 23 BY MR. STANOCH: 24 Q. Sure. Do you agree that the presence of 25 nitrosamines even at trace level is considered</p>

<p style="text-align: right;">Page 86</p> <p>1 unacceptable because these impurities are probable 2 human carcinogens? 3 MS. LOCKARD: Same objection. It's 4 outside of his scope, the class-certification expert 5 report. He is not here to give a causation opinion. 6 THE WITNESS: But in answer to your 7 question, Mr. Stanoch, no, I don't agree with that. 8 BY MR. STANOCH: 9 Q. Stand by. Stand by, sir. 10 You are familiar with the U.S. 11 Pharmacopeia Association, right, the USP? 12 A. Yes, Mr. Stanoch, I am. 13 Q. Yeah, you mean you used to be affiliated 14 with them, right? 15 A. I was an employee of USP between 2000 and 16 2014. 17 Q. Right. I'm going to mark another exhibit. 18 (Whereupon, Exhibit 4 was marked for 19 identification.) 20 BY MR. STANOCH: 21 Q. You are going to have to look on your 22 screen, unfortunately, Dr. Williams. I don't have a 23 copy of this in the binder available. 24 Can you pull it up, or would you like me 25 to share my screen? Exhibit 4.</p>	<p style="text-align: right;">Page 88</p> <p>1 MR. HARKINS: The exhibit share is what 2 you are talking about. 3 MS. LOCKARD: The exhibit-share box is 4 what I'm talking about. 5 THE WITNESS: Oh. 6 MR. HARKINS: Open the chat, Roger. 7 THE WITNESS: Oh. 8 (Whereupon, a brief discussion off the 9 record.) 10 THE WITNESS: Okay. I'm opening the chat 11 room, and -- 12 MR. HARKINS: Hold on. Let me -- someone 13 repaste the link to the exhibit share, please? 14 Sorry. Can someone please repaste the 15 link to the exhibit share? 16 All right. Can you hear me in the room? 17 MR. STANOCH: We can hear you, Steve. 18 THE VIDEOGRAPHER: I might be able to 19 retrieve it from the chat. 20 MR. HARKINS: Oh. I think that's it. 21 THE VIDEOGRAPHER: Okay. Yeah, you got 22 it. 23 MR. HARKINS: You control it here on the 24 separate screen, and you can scroll it down from 25 there.</p>
<p style="text-align: right;">Page 87</p> <p>1 A. Oh, I'll rely on you to give me something 2 that I can look at. 3 Q. Okay. Stand by, sir. 4 I'm now sharing my screen. This is 5 Exhibit 4 in the public folder. 6 Do you see this, sir? 7 A. Could we open the box and get it out of 8 the box? 9 MS. LOCKARD: Is it in the binder? 10 MR. STANOCH: It's not in the binder. I'm 11 sorry. 12 THE WITNESS: I think you are showing 13 me -- it looks like a PowerPoint; is that correct? 14 BY MR. STANOCH: 15 Q. Yeah, this is the -- correct. This is the 16 cover page of a webinar in which Naiffer Romero of 17 USP spoke on nitrosamine impurities? 18 A. Yeah, I don't see it very clearly. Can 19 you expand it or -- 20 MS. LOCKARD: Can you get it up out of the 21 box? 22 THE WITNESS: I don't -- 23 MR. STANOCH: It's not in the box, 24 Counsel, I'm sorry. 25 THE WITNESS: Not in the box.</p>	<p style="text-align: right;">Page 89</p> <p>1 THE WITNESS: Can I make it bigger? 2 MR. HARKINS: You should be able to zoom, 3 yeah. 4 THE WITNESS: Okay. I'm looking at it, 5 Mr. Stanoch. 6 BY MR. STANOCH: 7 Q. Okay. Great. 8 A. Please proceed. 9 Q. Sure. And you see the title page of this 10 slide, it's a USP webinar presentation? 11 A. I think I do see that, yes. 12 Q. All right. And then there is -- I have an 13 excerpt here, I have Slide 8 from that webinar on 14 the next page, if you scroll down, sir. The slide 15 says, "Background." 16 A. Okay. I'm looking at "Background." 17 Q. Great. And you will see that it's -- and 18 the highlighting, by the way, is original in the 19 document. I didn't modify this. 20 A. Okay. 21 Q. Do you see on the right it says, "Although 22 nitrosamines are also present in some foods and 23 drinking-water supplies, their presence in 24 medicines, even at trace level is considered 25 unacceptable because these impurities are probable</p>

<p style="text-align: right;">Page 90</p> <p>1 human carcinogens." Did I read that right?</p> <p>2 A. Yes, I think you read it correctly. And</p> <p>3 can you tell me the date of this document?</p> <p>4 Q. It's 2020.</p> <p>5 A. Oh, I see. All right. Thank you.</p> <p>6 Q. Uh-huh. And do you agree with that</p> <p>7 statement from this USP presentation?</p> <p>8 MS. LOCKARD: Objection. Asked and</p> <p>9 answered.</p> <p>10 THE WITNESS: I would say what I rely on</p> <p>11 is FDA's guidance document, which it does say you</p> <p>12 can have nitrosamine impurities within acceptable</p> <p>13 limits.</p> <p>14 BY MR. STANOCH:</p> <p>15 Q. Uh-huh.</p> <p>16 A. So I would not agree with this statement.</p> <p>17 Q. Okay. And you see there in the middle,</p> <p>18 there is a fake Post-it that says, "Purpose of ICH</p> <p>19 M7"; do you see that?</p> <p>20 A. Yes, I do see that.</p> <p>21 Q. It reads, "Provide a practical framework</p> <p>22 that is applicable to the identification</p> <p>23 categorization, qualification, and control of</p> <p>24 mutagenic impurities to limit potential carcinogenic</p> <p>25 risk." Did I read that right?</p>	<p style="text-align: right;">Page 92</p> <p>1 though, that a drug-substance or product</p> <p>2 manufacturer would follow ICH M7 guidance to</p> <p>3 identify, characterize, qualify, and control</p> <p>4 mutagenic impurities on its own, correct?</p> <p>5 A. It could do. I mean, I'm not a</p> <p>6 toxicologist, but my understanding is that there</p> <p>7 could be many mutagenic impurities beyond the</p> <p>8 nitrosamine impurities that we're considering in</p> <p>9 this matter.</p> <p>10 Q. Right. And it's the expectation that</p> <p>11 manufacturers on their own would work to identify,</p> <p>12 characterize, qualify, and control mutagenic</p> <p>13 impurities to limit potential carcinogenic risk,</p> <p>14 correct?</p> <p>15 MS. LOCKARD: Objection. Outside the</p> <p>16 scope of his class-certification opinions.</p> <p>17 THE WITNESS: Yes, and I'm certainly not</p> <p>18 debating with you the content of the M7 document,</p> <p>19 Mr. Stanoch. If you read statements from that, I</p> <p>20 would probably generally agree with your statements.</p> <p>21 BY MR. STANOCH:</p> <p>22 Q. Right. And you agree that it's the</p> <p>23 expectation that manufacturers would follow the ICH</p> <p>24 M7 guidance themselves, correct?</p> <p>25 MS. LOCKARD: Objection. Asked and</p>
<p style="text-align: right;">Page 91</p> <p>1 A. Yes, I think you are reading it correctly.</p> <p>2 Q. And would you agree with that statement</p> <p>3 about the purpose of ICH M7?</p> <p>4 A. Yes, that seems like a general statement,</p> <p>5 and I agree with it.</p> <p>6 Q. Right. And that would have been the case</p> <p>7 with ICH M7 guidance prior to the FDA's first take</p> <p>8 at establishing interim limits for nitrosamines in</p> <p>9 December 2018, correct?</p> <p>10 A. And although I didn't offer this as an</p> <p>11 opinion, I think FDA itself tended to follow the ICH</p> <p>12 M7 document, particularly with regard to the word</p> <p>13 "control." So when FDA is saying control, they are</p> <p>14 saying, we can put a limit on the NDMA impurity.</p> <p>15 Q. Well, the guidance is to the industry to</p> <p>16 deal with impurities when they find them in their</p> <p>17 drug substance or their drug products, right?</p> <p>18 A. Now, are you asking about M7?</p> <p>19 Q. Yes.</p> <p>20 A. Yes. And it's a general statement, but I</p> <p>21 think a specific example is the nitrosamine</p> <p>22 impurities, and that's what I alluded to in my</p> <p>23 report.</p> <p>24 Q. Right. Well, you mention control in the</p> <p>25 context of the FDA setting limits. The point is,</p>	<p style="text-align: right;">Page 93</p> <p>1 answered. Outside the scope.</p> <p>2 THE WITNESS: With the exception of</p> <p>3 nitrosamine, where, if I may say so, FDA did the</p> <p>4 work of M7 on behalf of the entire industry.</p> <p>5 BY MR. STANOCH:</p> <p>6 Q. Well, prior to December 2018 there were no</p> <p>7 FDA interim limits, right?</p> <p>8 A. That's true.</p> <p>9 Q. Okay. But we had ICH M7 guidance,</p> <p>10 correct?</p> <p>11 A. Yes.</p> <p>12 Q. And the guidance set forth that</p> <p>13 manufacturers should identify, characterize,</p> <p>14 qualify, and control mutagenic impurities to limit</p> <p>15 potential carcinogenic risk, yes?</p> <p>16 A. I'm not debating the words of the</p> <p>17 guidance, if that's your question. I agree with the</p> <p>18 words of the guidance.</p> <p>19 Q. Well, I'm asking you about the application</p> <p>20 of the guidance, Dr. Williams, that even in the</p> <p>21 absence of the FDA interim limits in December 2018,</p> <p>22 was the expectation that a manufacturer would still</p> <p>23 attempt to identify, characterize, qualify, and</p> <p>24 control mutagenic impurities to limit potential</p> <p>25 carcinogenic risk?</p>

<p style="text-align: right;">Page 94</p> <p>1 MS. LOCKARD: Objection. Vague. Outside 2 the scope. 3 THE WITNESS: Yeah, I didn't really 4 comment on this, Mr. Stanoch. Do you want me to 5 speculate? 6 BY MR. STANOCH: 7 Q. I would like you to answer the question, 8 Dr. Williams. 9 A. You know, the way I would say it, and I 10 think I have already alluded to this previously, is, 11 you know, an ANDA applicant generally follows the 12 guidances I cited in my report. 13 And to the extent that they -- you know, 14 when they get into qualifying an impurity, they may 15 have to consider mutagenic or DNA-reactive 16 impurities, and then they would turn to the M7 17 guidance. But that is certainly a case-by-case 18 decision, and you would have to suspect the impurity 19 was present and you would have to be able to measure 20 it. So you are asking a very general question. 21 Q. And the ICH M7 guidance is not confined to 22 ANDA applications, correct? 23 A. That's my understanding. Again, if you 24 are going to ask me questions about it, it would 25 probably be best if I could see it.</p>	<p style="text-align: right;">Page 96</p> <p>1 the lines of your questioning. 2 Q. So you can't tell me one way or the other 3 about whether the ICH M7 guidance applies throughout 4 the life of a drug? 5 MS. LOCKARD: Objection. Asked and 6 answered. 7 He said if you are going to ask him 8 questions about the application and interpretation 9 of the guidance, he wants to have it in front of 10 him, which is a fair request. 11 BY MR. STANOCH: 12 Q. You can answer the question, Dr. Williams. 13 MS. LOCKARD: Objection. It's 14 argumentative. 15 THE WITNESS: I prefer not to answer the 16 question without seeing the guidance. 17 BY MR. STANOCH: 18 Q. And which guidance do you want to see, 19 Doctor? 20 A. M7. 21 Q. What version? 22 A. The current version. 23 Q. What year? 24 A. I think it's 2015. 25 Q. Show me where it is in your reliance</p>
<p style="text-align: right;">Page 95</p> <p>1 Q. Well, we will get to specific parts of it, 2 but -- your understanding that the ICH M7 guidance 3 applies to the life of a drug from application 4 through commercialization, correct? 5 A. Again, you know, I feel very uncomfortable 6 answering questions about a document that I haven't 7 seen and that I cite in my report, but I would say 8 it was not particularly important to my opinions. 9 But again, you know, I'll be glad to walk 10 through it with you, Mr. Stanoch. I don't think it 11 is particularly appropriate for my opinions or 12 important to my opinions, but again, I'm certainly 13 here to be responsive to your questions. 14 Q. Right. And you agree that the ICH M7 15 guidance applies throughout the life of a drug, 16 correct? 17 A. I don't believe I said that. I think what 18 I said is if we're going -- if you are going to ask 19 me that question, I feel like I need to see the 20 guidance. 21 Q. You can't tell me anything about the ICH 22 M7 guidance general applicability without looking at 23 it? 24 A. I think, yes, I'm saying that. I would be 25 hesitant to make statements about the guidance along</p>	<p style="text-align: right;">Page 97</p> <p>1 materials and report, which version you want. 2 MS. LOCKARD: Let me just put an objection 3 on the record. You are asking him questions about a 4 guidance that you haven't identified. He is asking 5 to see the guidance that you were questioning him 6 about. If you want to question him about a 7 document, identify it. Now you are telling him 8 to -- 9 MR. STANOCH: Counsel, enough. Enough, 10 Counsel. Counsel, enough. 11 (Overlapping speakers.) 12 MR. STANOCH: I'm asking him to tell me 13 the document he wants. I'm asking him to tell me 14 what document he wants. I'm trying to comply with 15 his request, Counsel. Please, let him tell me what 16 he wants to see. Thank you. 17 We have lost Dr. Williams. Dr. Williams, 18 we can't see you. 19 MS. LOCKARD: We're on break. We can go 20 off the record. You can keep running. 21 MR. STANOCH: Wait a minute. Wait a 22 minute. Wait a minute. Wait a minute. I am not 23 agreeing to go off the record. I have a pending 24 question to the witness to tell me what document he 25 said he needs to see. I am not agreeing to go off</p>

<p style="text-align: right;">Page 98</p> <p>1 the record.</p> <p>2 Q. Are you going to answer the question,</p> <p>3 Dr. Williams?</p> <p>4 MR. STANOCH: Or, Counsel, are you going</p> <p>5 to instruct him not to answer it?</p> <p>6 Well, let it be noted that despite the</p> <p>7 nonagreement and the pending question, both the</p> <p>8 witness and counsel have gone off.</p> <p>9 Let's keep running.</p> <p>10 THE WITNESS: I have been instructed by</p> <p>11 counsel to come back, Mr. Stanoch, and now I'm</p> <p>12 trying to look for the guidance that you are</p> <p>13 alluding to.</p> <p>14 MR. STANOCH: Thank you.</p> <p>15 THE WITNESS: And I would say we can look,</p> <p>16 if you agree, to the guidance for industry</p> <p>17 genotoxic -- the other one -- I would really</p> <p>18 appreciate it if you would pick the guidance because</p> <p>19 you are talking about it. But yes, here it is.</p> <p>20 I have been handed it in a copy. M7,</p> <p>21 Revision 1, Addendum to ICH M7. Now, that makes me</p> <p>22 a little nervous because it's an addendum, and it</p> <p>23 makes me wonder, where is the M7(R1)? But if we can</p> <p>24 look at M7(R1), I'll be glad to answer questions</p> <p>25 about it if I can.</p>	<p style="text-align: right;">Page 100</p> <p>1 benefit of all of your colleagues on Zoom. Well,</p> <p>2 that's going to take me time.</p> <p>3 Q. Doctor, I can pull up the March 2018</p> <p>4 guidance. You want to work with that for now? Or</p> <p>5 would --</p> <p>6 A. And I also think it would be important to</p> <p>7 go to my report where I reference this document.</p> <p>8 Let me see if I can find that.</p> <p>9 MS. LOCKARD: And while he is doing that,</p> <p>10 Exhibit 4 was the USP PowerPoint. It looks like</p> <p>11 there are only two pages of that. Do you have</p> <p>12 the -- are you making the full PowerPoint the</p> <p>13 exhibit?</p> <p>14 MR. STANOCH: Those are excerpts from the</p> <p>15 webinar. We will mark the entire webinar.</p> <p>16 Q. Well, Doctor, let's see if we can cut</p> <p>17 through this a little bit, shall we? You agree, do</p> <p>18 you not, that ICH M7 guidance has been in effect --</p> <p>19 has been effective in different forms for quite some</p> <p>20 time, yes?</p> <p>21 A. I can agree with that, Mr. Stanoch,</p> <p>22 please, if the --</p> <p>23 Q. Sure. Sure. And why don't we get a</p> <p>24 ballpark. I mean, can we say that at least since</p> <p>25 2003 there has been some form of ICH M7 guidance?</p>
<p style="text-align: right;">Page 99</p> <p>1 BY MR. STANOCH:</p> <p>2 Q. I'm --</p> <p>3 A. Can you proceed, Mr. Stanoch?</p> <p>4 Q. Well, I want to make sure we have the</p> <p>5 right documents in front of us, and I have to mark</p> <p>6 it, Dr. Williams. So why don't you tell me the date</p> <p>7 of the document you are looking at?</p> <p>8 A. Well, what I have been handed is M7(R1),</p> <p>9 dated March 31st, 2017, and then a M7(R1) addendum,</p> <p>10 so it's lot of paper and I'm looking at two</p> <p>11 documents.</p> <p>12 MS. LOCKARD: And for the record, I still</p> <p>13 don't know what it is that your question is asking</p> <p>14 about, so we are trying to print whatever we think</p> <p>15 you are asking about, but you have refused so far to</p> <p>16 identify -- counsel has refused to identify the</p> <p>17 specific guidance that he is asking the doctor to</p> <p>18 interpret, so --</p> <p>19 THE WITNESS: Okay. I'm prepared to</p> <p>20 answer questions. Did you get the dates of the</p> <p>21 documents I'm looking at? The M7, Revision 1, is</p> <p>22 March 2017.</p> <p>23 MS. LOCKARD: Can you hear us?</p> <p>24 MR. STANOCH: Yeah, I'm trying to pull up</p> <p>25 the version that you have in the hard copy for the</p>	<p style="text-align: right;">Page 101</p> <p>1 A. You know, I'd hesitate from that, but for</p> <p>2 purpose of a discussion let me agree so that we can</p> <p>3 go forward.</p> <p>4 Q. I appreciate that. I won't hold you to</p> <p>5 the particular date. I was just trying to pick a</p> <p>6 date that we could just move forward from. So --</p> <p>7 and we can agree, can we not, that there has been</p> <p>8 revisions and addenda to the M7 guidance over time,</p> <p>9 correct?</p> <p>10 A. Okay. Let me agree.</p> <p>11 Q. And would you agree that even in the</p> <p>12 absence of FDA interim limits for nitrosamines,</p> <p>13 there was an expectation that a manufacturer would</p> <p>14 adhere to the ICH M7 guidance concerning genotoxic</p> <p>15 impurities, whatever the status of that guidance was</p> <p>16 at the particular time?</p> <p>17 MS. LOCKARD: Objection. These are</p> <p>18 liability opinions and outside the scope of his</p> <p>19 report.</p> <p>20 THE WITNESS: Yeah, I am very hesitant</p> <p>21 with your general statements, but again, I won't</p> <p>22 contest them so we can move forward. Go ahead,</p> <p>23 Mr. Stanoch.</p> <p>24 BY MR. STANOCH:</p> <p>25 Q. I'm a little unclear what you mean by</p>

<p style="text-align: right;">Page 102</p> <p>1 don't contest them. Does that mean you will agree 2 with that question? 3 MS. LOCKARD: Objection. Vague. 4 THE WITNESS: You know, it would be 5 much -- can you restate the question? 6 BY MR. STANOCH: 7 Q. Sure. Would you agree that even in the 8 absence of FDA interim limits for nitrosamines, 9 there was an expectation that a manufacturer would 10 adhere to the ICH M7 guidance concerning genotoxic 11 impurities as that guidance stood at the particular 12 time? 13 MS. LOCKARD: Objection. Vague. Outside 14 the scope of his expert report. 15 THE WITNESS: Yes, it's not any opinion I 16 offered, but I won't debate what you are saying, so 17 I can agree with it, Mr. Stanoch. 18 BY MR. STANOCH: 19 Q. Fair enough. And do you agree that the 20 ICH M7 guidance includes nitrosamines in the cohort 21 of concern? And if you need to look at the version 22 in front of you, that's fine, and we could mark it 23 later. 24 A. I don't know where I see nitrosamines 25 here, and I didn't look for it.</p>	<p style="text-align: right;">Page 104</p> <p>1 reading anything correctly. 2 THE WITNESS: No, okay. 3 All right. Well, I'm a little hesitant 4 about answering, Mr. Stanoch. 5 MR. STANOCH: Then stand by for an 6 exhibit, sir. 7 I'm going to mark the next exhibit, sir. 8 (Whereupon, Exhibit 5 was marked for 9 identification.) 10 BY MR. STANOCH: 11 Q. Exhibit 5. This is actually Tab 2 in your 12 binder. You can take the binder out of the box we 13 sent you as a courtesy. 14 MS. LOCKARD: Hold on. We are opening the 15 box. There is one black binder in here. Tab 2? 16 MR. STANOCH: Yes, please. 17 MS. LOCKARD: Okay. 18 BY MR. STANOCH: 19 Q. Tell me when you have that, Doctor. 20 A. I think I'm looking at it. Tab 2, it is a 21 letter from FDA to -- I don't see who it's to. But 22 it looks to be about a five-page letter. 23 Q. Right. It's a general advice letter from 24 the FDA. You see that in the upper right, "General 25 Advice"?</p>
<p style="text-align: right;">Page 103</p> <p>1 Q. All right. Let -- 2 A. Can you point it out where you see it, 3 Mr. Stanoch? 4 Q. Sure. Put that aside, then. Let's put it 5 a different way. Are you aware that the FDA has 6 stated that N-nitroso compounds are identified as a 7 cohort of concern in ICH M7 guidance? 8 MS. LOCKARD: Objection. Outside the 9 scope of his expert report. 10 THE WITNESS: Yeah, I see no reason to 11 deny what you are saying, so I'll agree with it to 12 continue the discussion, Mr. Stanoch. 13 BY MR. STANOCH: 14 Q. Thank you. I appreciate that, Doctor. 15 And a substance that falls within the ICH 16 cohort of concern should be controlled, correct? 17 MS. LOCKARD: Objection. Falls outside of 18 the scope of his class-certification opinions. 19 THE WITNESS: You know, I could probably 20 agree more readily if you could show me where you 21 are reading in the guidance. But again, for 22 purposes of the discussion, I won't debate what you 23 are saying, Mr. Stanoch. I'm sure you are reading 24 it correctly. 25 MS. LOCKARD: I wouldn't assume that he is</p>	<p style="text-align: right;">Page 105</p> <p>1 A. I do see that. 2 Q. Uh-huh. And do you see -- 3 MS. LOCKARD: There is no Bates number, 4 for those on the call. 5 BY MR. STANOCH: 6 Q. Would you look at the last paragraph of 7 the first page, sir? 8 A. Last paragraph, first page. 9 Q. It begins, "Nitrosamine compounds." Do 10 you see that? 11 A. Wait a minute. Oh, "Nitrosamine 12 compounds." Yes, I'm with you, Mr. Stanoch. Go 13 ahead. 14 Q. Wonderful. Why don't you read for us the 15 first few sentences of that paragraph? 16 A. "Nitrosamine compounds are potent 17 genotoxic carcinogens in several nonclinical species 18 and are classified as probable human carcinogens by 19 the International Agency for Research on Cancer. In 20 fact, 'N-nitroso' compounds are identified as a 21 'cohort of concern' in internationally" recognized 22 "guidance, ICH M7," and then it states the name. 23 Should I stop there? 24 Q. Keep going. Slowly, please, for the court 25 reporter.</p>

<p style="text-align: right;">Page 106</p> <p>1 A. "ICH M7 recommends that known mutagenic 2 carcinogens, such as nitrosamines," to "be 3 controlled at or below the acceptable cancer risk 4 level. Due to their known potent carcinogenic 5 effects, and because it is feasible to limit these 6 impurities by taking reasonable steps to prevent or 7 eliminate their presence, FDA has determined that 8 there is no acceptable specification for 9 nitrosamines in ARB API and DP." 10 Q. That's fine. Okay. And, oh, actually, 11 why don't you read the one more sentence? 12 A. "Therefore, FDA advises that nitrosamines 13 should be absent (not detectable as described below) 14 from ARB API and ARB drug products." 15 Q. Okay. Thank you. 16 So, first of all, were you aware of this 17 general advice letter from the FDA prior to right 18 now? 19 A. No. 20 Q. Okay. Second of all, do you agree with 21 the FDA's statement in this letter that nitrosamine 22 compounds are potent genotoxic carcinogens? 23 MS. LOCKARD: Objection. Outside the 24 scope of his class-certification opinions. He is 25 not here to give a causation opinion.</p>	<p style="text-align: right;">Page 108</p> <p>1 And the next sentence, do you agree with 2 the FDA that N-nitroso compounds are part of the 3 cohort of concern under ICH M7 guidance? 4 A. Yes, I see the words, and I think you are 5 reading them correctly. 6 Q. And do you agree with that statement, 7 regardless of whether I read it correctly? 8 MS. LOCKARD: Does he agree that it -- 9 right. Objection. Vague. 10 THE WITNESS: I see no reason to disagree 11 with the words in this letter. 12 BY MR. STANOCH: 13 Q. Perfect. And do you agree, then, that as 14 part of the cohort of concern, nitrosamines should 15 be controlled? 16 A. Yes, I can agree with that. 17 Q. All right. And do you agree generally 18 that nitrosamines can be controlled? 19 A. Yes, I think FDA documented that in its 20 December 2018 statement. 21 Q. And do you agree that nitrosamines can be 22 avoided entirely? 23 A. You know, that's sort of a case-by-case 24 question. 25 But what is perplexing me about this</p>
<p style="text-align: right;">Page 107</p> <p>1 THE WITNESS: And I know I'm not supposed 2 to ask questions, but I don't see a date on this 3 letter. Is there a date? 4 BY MR. STANOCH: 5 Q. It doesn't appear that it has a date on 6 it. 7 A. And also, if I may say so, I think this 8 conflicts with the FDA guidance on nitrosamine 9 impurities, but we can have that conversation if you 10 wish. 11 But anyway, back to you, Mr. Stanoch. Am 12 I answering your questions about this document? 13 Q. Well, not yet. The question was: Do you 14 agree with the FDA's statement that nitrosamine 15 compounds are potent genotoxic carcinogens? 16 MS. LOCKARD: Objection. Outside the 17 scope of his class-certification opinions. He is 18 not here to give a causation opinion. 19 THE WITNESS: Yes, and I'm not going to 20 debate the wording in this letter. It seems like a 21 formal letter from the agency, and I'm not in a 22 position to disagree with FDA on this point. 23 So please continue, Mr. Stanoch. 24 BY MR. STANOCH: 25 Q. I certainly will. Thank you, Doctor.</p>	<p style="text-align: right;">Page 109</p> <p>1 letter is I think the FDA guidance says you can have 2 nitrosamine impurities as long as they stay within 3 the acceptable intake limits. 4 Q. Uh-huh. 5 A. So I see a dissonance between this letter 6 and the FDA guidance. 7 Q. Uh-huh. 8 A. But please continue. 9 Q. And you say "a case-by-case basis." Do 10 you mean by that that it would be on a particular 11 manufacturer to assess whether nitrosamines could be 12 avoided entirely in its manufacturing process? 13 A. Yes, I agree with the way you stated that. 14 Thank you. 15 Q. Uh-huh. Yep. And were you aware prior to 16 seeing this letter that at one point the FDA said 17 that it had determined that there is no acceptable 18 specification for nitrosamines in ARB API and DP? 19 A. Well, as I say, I think that's not what 20 the guidance says, but I see where it says it here 21 in this letter. 22 Q. Uh-huh. You keep saying "guidance." 23 Which guidance do you mean specifically? 24 A. It was the nitrosamine impurities guidance 25 that I cite in my report. It came out in September</p>

<p style="text-align: right;">Page 110</p> <p>1 of 2020, and then it was updated in February of 2 2021. 3 Q. Uh-huh. So at the time this FDA general 4 advice letter was put out, it was the FDA's view 5 that there is no acceptable specification for 6 nitrosamines in ARB API and DP, correct? 7 A. Yes, and we don't quite know when because 8 we can't see a date on this letter. 9 Q. Well, I believe the letter was from 10 sometime in 2019. 11 MS. LOCKARD: Objection to counsel 12 testifying. 13 BY MR. STANOCH: 14 Q. Assume the letter was from 2019, Doctor, 15 okay? 16 A. Okay. I'm willing to make that 17 assumption. It may have come out, then -- 18 Q. Great. 19 A. It may have come out, then, before the 20 first iteration of the draft September 2020 21 guidance, and therefore the guidance superseded this 22 document. 23 Q. Sure. Then -- 24 A. That would resolve my dissonance. 25 Q. And that may be the sequence of events,</p>	<p style="text-align: right;">Page 112</p> <p>1 MS. LOCKARD: What paragraph are you 2 looking at? 3 MR. STANOCH: Same one. 4 THE WITNESS: Uh-huh. Well, we can keep 5 on looking at this letter. Is there a question 6 pending, Mr. Stanoch? 7 BY MR. STANOCH: 8 Q. There was. The FDA goes on to say they 9 used the interim limits only to guide immediate 10 decision-making for the product recalls. Do you see 11 that? 12 A. I do see that. 13 Q. Uh-huh. And were you aware of that prior 14 to today? 15 MS. LOCKARD: Objection. Vague. 16 THE WITNESS: And this is the first time I 17 have seen this letter. 18 BY MR. STANOCH: 19 Q. Okay. Let's put that aside for now, 20 Doctor. 21 A. Okay. Thank you. 22 Q. Why don't you flip to Tab 3 in your 23 binder. It will be introduced as Exhibit 6. 24 (Whereupon, Exhibit 6 was marked for 25 identification.)</p>
<p style="text-align: right;">Page 111</p> <p>1 Doctor. But at the time this letter came out, 2 right, the FDA had determined there is no acceptable 3 specification for nitrosamines in ARB API and DP, 4 right? 5 A. I see the wording in the letter. I don't 6 disagree with the way you are stating the wording. 7 And I'm willing to make the assumption it came out 8 sometime in 2019. 9 Q. So then, at the time of this letter, there 10 should be no nitrosamines in any valsartan API or 11 drug product, correct? 12 MS. LOCKARD: Objection. Vague. 13 Foundation. 14 THE WITNESS: Well, I think FDA is even 15 saying in this letter that they provided interim 16 acceptable limits for nitrosamine impurities in 17 ARBs. So I don't know how to kind of piece together 18 what it's saying here versus, well, the other 19 realities of their December 2018 decision and the 20 guidance that I cited in my report. 21 BY MR. STANOCH: 22 Q. Uh-huh. The FDA goes on to say that they 23 used the interim limits only to guide immediate 24 decision-making for the product recalls. Do you see 25 that?</p>	<p style="text-align: right;">Page 113</p> <p>1 BY MR. STANOCH: 2 Q. Tell me when you are there, Doctor. 3 A. I'm there. I see it. M7(R1). Is that 4 what we're talking about, March 2018? 5 Q. Yes, sir. We're on the same document. 6 That's a good step. So are you familiar with this 7 document? 8 A. I'm aware of it. I did not study it 9 closely for my report. 10 Q. That's okay. But you understand that it's 11 the ICH guidance as of March 2018, correct? 12 A. Yes, I do. And then the one I had printed 13 out for me before was dated 31 March 2017. 14 Q. Right. And I don't have a copy of exactly 15 what you were handed. We can get it. 16 But this goes back to our point that the 17 guidance might have went through various iterations 18 over time generally, right? 19 A. Yes, exactly. That's how the ICH 20 guidances work. So I'm prepared to consider this 21 with you, Mr. Stanoch. 22 Q. That's great. So why don't we turn to 23 page 5 of this document, sir? 24 A. All right. 25 Q. And tell me when you are there.</p>

<p style="text-align: right;">Page 114</p> <p>1 A. I'm there. Where it says, "General 2 Principles"? 3 Q. Yes, sir. And then you see the paragraph 4 in the middle, "A Threshold of Toxicological 5 Concern"? 6 A. I do see that. 7 Q. Uh-huh. And do you see at the end that 8 this March 2018 guidance states, "This group of high 9 potency mutagenic carcinogens, referred to as the 10 cohort of concern, comprises aflatoxin-like-, 11 N-nitroso-, and alkyl-azoxy compounds," correct? 12 A. Yes, I do see that. 13 Q. All right. And N-nitroso compounds, those 14 would include the NDMA and NDEA nitrosamines that 15 you discuss in your report, correct? 16 A. I think you are saying that correctly. 17 Thank you, Mr. Stanoch. 18 Q. And then what is your understanding of 19 cohort of concern, sir? 20 A. As the words say here, it's a group of 21 high-potency mutagenic carcinogens that comprises 22 the three -- excuse me, Mr. Stanoch -- that 23 comprises the three types of compounds stated in the 24 sentence. A cohort of concern, apparently they are 25 trying to classify some particularly mutagenic</p>	<p style="text-align: right;">Page 116</p> <p>1 beginning of the paragraph, it says, "was developed 2 to define an acceptable intake for any unstudied 3 chemical that poses a negligible risk." So I guess 4 if it is below the threshold, the risk is 5 negligible, but if it is above, you begin to have 6 some concern. Please correct me if -- 7 BY MR. STANOCH: 8 Q. Right. I apologize. Are you done, 9 Doctor? 10 A. Yes, I think I am. Thank you, 11 Mr. Stanoch. 12 Q. Yes. And just following along, you see 13 later in that paragraph it says, "For application of 14 a TTC in the assessment of acceptable limits of 15 mutagenic impurities," and the sentence continues. 16 Do you see that? 17 A. I do. 18 Q. Right. And the purpose of the TTC was to 19 assess acceptable limits of impurities in drug 20 substances, correct? 21 MS. LOCKARD: Objection. Outside the 22 scope of his expert opinion. You are asking him 23 what the purpose of the TTC was. This is not part 24 of his class-certification report. 25 THE WITNESS: Yeah, and -- the only thing</p>
<p style="text-align: right;">Page 115</p> <p>1 carcinogens, as stated here in the sentence. 2 Q. And the purpose of that is to alert 3 industry that limits for the cohort of concern might 4 be much lower than the threshold of toxicological 5 concern that might otherwise be defined per the 6 guidance, right? 7 MS. LOCKARD: Objection. Vague. And 8 outside the scope of his testimony. 9 THE WITNESS: Yeah. And you are beginning 10 to ask me questions that I would call 11 pharmacology/toxicology questions. 12 I can read the sentences here and agree 13 with them, Mr. Stanoch. For example, it says, "Some 14 structural groups were identified to be of such high 15 potency," and then the sentence continues. And 16 these high potency are referred to as a cohort of 17 concern, and then it lists the three compounds that 18 fall into the structural categories that we have 19 already discussed. 20 BY MR. STANOCH: 21 Q. Uh-huh. And then the threshold of 22 toxicological concern, what does that relate to? 23 MS. LOCKARD: Objection. Vague. Outside 24 the scope. 25 THE WITNESS: Well, if we go back to the</p>	<p style="text-align: right;">Page 117</p> <p>1 I can do is read the words and sort of say I have a 2 general understanding of what they are saying. I'm 3 certainly not a pharmacologist-toxicologist. 4 BY MR. STANOCH: 5 Q. I'm not asking for a pharmacology or 6 toxicology opinion, Doctor. I'm asking your 7 understanding in the context of a report where you 8 talk about thresholds of limits that may or may not 9 have existed. 10 We're looking now here at the ICH 11 guidance, the March 20th, 2018, version, and it's 12 talking about acceptable limits of mutagenic 13 impurities, right? 14 A. But I still don't see limits. Am I 15 missing limits? 16 Q. Well, the whole thrust is talking about 17 assessment of acceptable limits, is it not? 18 A. I think it's talking about it generally, 19 but when I spoke about it in my report, I was 20 talking specifically about the limits that FDA 21 created in December 2018 and nothing more. 22 Q. Right. And what I'm getting at, Doctor, 23 is: Prior to the FDA's interim limits, there 24 already was industry guidance on acceptable limits 25 of mutagenic impurities, correct?</p>

<p style="text-align: right;">Page 118</p> <p>1 MS. LOCKARD: Objection. Outside the 2 scope of his opinions. 3 THE WITNESS: If you are talking about 4 this document, I would certainly agree with you. 5 BY MR. STANOCH: 6 Q. Great. And you would agree for any other 7 iteration of this M7(R1) guidance prior to this one 8 that spoke of acceptable limits of mutagenic 9 impurities as well, correct? 10 A. Well, that's a broad statement, but again, 11 let me agree for purposes of discussion. 12 Q. I appreciate that. And then let's flip to 13 page 14. Let me know when you are there, sir. 14 A. Okay. I'm there. 15 Q. And do you see Section E, sir? 16 A. I do. 17 Q. Right. And do you see there is three 18 bullets under Section E? 19 A. I do. 20 Q. And the third bullet is talking about the 21 cohort of concern impurities again, fair? 22 A. I see that, yes. 23 Q. And it notes, "If these compounds are 24 found as impurities in pharmaceuticals, acceptable 25 intakes for these high-potency carcinogens would</p>	<p style="text-align: right;">Page 120</p> <p>1 what we're talking about, what are the acceptable 2 intake limits. And I think FDA has -- they provided 3 those in December 2018. That's what I stated in my 4 report. 5 Q. You -- 6 A. You know, as long as we're sort of looking 7 at this ad hoc document that I did not study or cite 8 in my report other than to notice its availability, 9 Mr. Stanoch, I might draw your attention to the 10 first bullet on this page, where it says, "Higher 11 acceptable intakes may be justified when human 12 exposure to the impurity will be much greater from 13 other sources, e.g., food." Now, of course that's 14 exactly the case with nitrosamines. 15 Q. Well, thank you for the gratuitous 16 statement, Doctor, but let's talk about that. 17 All three of these bullets we are looking 18 at, flexibilities in approaches, they are suggesting 19 to manufacturers to conduct a case-by-case approach 20 to come up with acceptable intake limits for 21 products, correct? 22 A. Yes, and in the case of nitrosamines, in 23 the current matter, FDA did that for manufacturers, 24 as the prior letter you showed me noticed, in 25 December 2018.</p>
<p style="text-align: right;">Page 119</p> <p>1 likely be significantly lower than the acceptable 2 intakes defined in this guidance." 3 Did I read that right? 4 A. I can agree with your reading of the 5 words. 6 Q. Uh-huh. Right. And then you see it 7 further says, "Although the principles of this 8 guidance can be used, a case-by-case approach 9 using," for example, "carcinogenicity data from 10 closely related structures, if available, should 11 usually be developed to justify acceptable intakes 12 for pharmaceutical development and marketed 13 products." 14 Did I read that correctly? 15 A. I think you are reading it correctly, yes, 16 no question about that. 17 Q. I appreciate that, Doctor. 18 And so what the guidance we're looking at 19 here is saying is that for the cohort of concern 20 impurities, which includes the nitrosamine 21 compounds, at least as of the date of this guidance 22 of March 2018, that acceptable intake limits for it 23 should be developed for both the development and 24 marketing of pharmaceutical products? 25 A. Well, I agree with you. I think that's</p>	<p style="text-align: right;">Page 121</p> <p>1 Q. Right. Well, prior to the FDA's interim 2 limits for nitrosamines in December of 2018, there 3 already was industry guidance, was there not, that 4 manufacturers should be conducting their own 5 assessments to potentially set limits for impurities 6 such as nitrosamines? 7 MS. LOCKARD: Objection. Outside the 8 scope of his class-certification opinions. 9 THE WITNESS: Yes, and remember, we're 10 dealing with a situation where FDA said this was 11 unexpected, they didn't know how it occurred. They 12 had many other caveats that indicated, if you will, 13 their surprise that came about in the summer of 14 2018. These are very low-level impurities, and you 15 would have to suspect them and then have analytical 16 capability to identify them, notwithstanding all the 17 words in this guidance. 18 So I'm glad to walk through the guidance 19 with you. I think it's an interesting and important 20 guidance, Mr. Stanoch, but it really only is 21 tangentially related to my report. 22 BY MR. STANOCH: 23 Q. So it's not important to your opinions 24 that there already was industry guidance on how to 25 address levels of nitrosamines in drugs prior to the</p>

<p style="text-align: right;">Page 122</p> <p>1 December 2018 FDA interim guidance?</p> <p>2 MS. LOCKARD: Objection. Outside of the</p> <p>3 scope of his opinions. That's not what he was</p> <p>4 retained, that's not what he discussed in his expert</p> <p>5 report.</p> <p>6 THE WITNESS: Yeah, I'm listening to the</p> <p>7 two counsel, and I think the way you both said it is</p> <p>8 correct. I was considering other factors and</p> <p>9 information that I cited in my report that led to my</p> <p>10 opinions, and I certainly haven't changed my</p> <p>11 opinions as a result of the review of this document.</p> <p>12 BY MR. STANOCH:</p> <p>13 Q. Okay. Are you aware of any Novartis</p> <p>14 Diovan product sold in the --</p> <p>15 (Reporter clarification.)</p> <p>16 MR. STANOCH: No problem. Let's start</p> <p>17 over.</p> <p>18 Q. Are you aware of any Novartis Diovan</p> <p>19 product sold in the United States that contained</p> <p>20 NDMA?</p> <p>21 A. I am not.</p> <p>22 Q. Are you aware of any Novartis Diovan</p> <p>23 product sold in the United States that contained</p> <p>24 NDEA?</p> <p>25 A. No, I am not.</p>	<p style="text-align: right;">Page 124</p> <p>1 to June 20, 2018, but Teva could not?</p> <p>2 MS. LOCKARD: Objection. Outside the</p> <p>3 scope of his expert opinion on class-certification</p> <p>4 issues. Vague. Lacks foundation. Argumentative.</p> <p>5 THE WITNESS: Again, Mr. Stanoch, I just</p> <p>6 have not seen any documents to that point. If you</p> <p>7 can point to them in my materials considered, I</p> <p>8 would be glad to look at them with you.</p> <p>9 BY MR. STANOCH:</p> <p>10 Q. Uh-huh. Well, you tell me, Doctor, did</p> <p>11 you look at any materials that identify how Novartis</p> <p>12 was able to discover NDMA in ZHP's valsartan API?</p> <p>13 MS. LOCKARD: Objection. Outside the</p> <p>14 scope of his class-certification opinions. Lacks</p> <p>15 foundation. Speculation.</p> <p>16 THE WITNESS: And my apologies,</p> <p>17 Mr. Stanoch. I thought I had answered that</p> <p>18 question. I have not seen any documents, anywhere,</p> <p>19 that speak to Novartis' testing of any products for</p> <p>20 nitrosamines.</p> <p>21 BY MR. STANOCH:</p> <p>22 Q. Can you tell me what methods Novartis used</p> <p>23 to detect NDMA in ZHP's valsartan API?</p> <p>24 MS. LOCKARD: Objection. Outside the</p> <p>25 scope of his class-certification opinions. Lacks</p>
<p style="text-align: right;">Page 123</p> <p>1 Q. You are aware, are you not, that Novartis</p> <p>2 detected NDMA in ZHP's valsartan API prior to</p> <p>3 June 20th, 2018, correct?</p> <p>4 A. You know, I have heard statements to that</p> <p>5 effect from counsel, but I don't think I have ever</p> <p>6 seen any documents for it. I don't think a document</p> <p>7 exists on my materials-considered list, and I</p> <p>8 certainly didn't cite anything like that in my</p> <p>9 report.</p> <p>10 Q. Uh-huh. Can you tell us how --</p> <p>11 A. But I would be glad to look at such a</p> <p>12 document if you have it, Mr. Stanoch.</p> <p>13 Q. Uh-huh. Can you tell us how Novartis was</p> <p>14 able to identify NDMA in ZHP's valsartan API prior</p> <p>15 to June 20, 2018?</p> <p>16 MS. LOCKARD: Objection. Outside the</p> <p>17 scope of his expert opinions on class certification.</p> <p>18 Lacks foundation. Speculation.</p> <p>19 THE WITNESS: You know, I'm not,</p> <p>20 Mr. Stanoch. I just don't have any documents to</p> <p>21 speak to that. I would be glad to look at them if</p> <p>22 you have them.</p> <p>23 BY MR. STANOCH:</p> <p>24 Q. Uh-huh. Can you tell us how Novartis was</p> <p>25 able to identify NDMA in ZHP's valsartan API prior</p>	<p style="text-align: right;">Page 125</p> <p>1 foundation. Speculation.</p> <p>2 THE WITNESS: No, I cannot, Mr. Stanoch.</p> <p>3 BY MR. STANOCH:</p> <p>4 Q. You cannot tell me why Novartis would have</p> <p>5 a method for detecting NDMA in ZHP's valsartan API,</p> <p>6 can you?</p> <p>7 MS. LOCKARD: Objection. Outside the</p> <p>8 scope of his class-certification opinions. Lacks</p> <p>9 foundation. Calls for speculation.</p> <p>10 THE WITNESS: No, I can't, Mr. Stanoch.</p> <p>11 BY MR. STANOCH:</p> <p>12 Q. Why would -- strike that. Start over.</p> <p>13 Why would Novartis be testing ZHP's</p> <p>14 valsartan API for NDMA in the first place?</p> <p>15 MS. LOCKARD: Objection. Outside the</p> <p>16 scope of his class-certification opinions. Calls</p> <p>17 for speculation. Lacks foundation.</p> <p>18 THE WITNESS: I just have no idea,</p> <p>19 Mr. Stanoch. It would be guessing, and I could only</p> <p>20 guess.</p> <p>21 BY MR. STANOCH:</p> <p>22 Q. Well, there is no specification in the</p> <p>23 Diovan monograph, for example, for nitrosamines,</p> <p>24 right?</p> <p>25 A. When you say "Diovan monograph," I assume</p>

<p style="text-align: right;">Page 126</p> <p>1 you are talking about the USP monographs for 2 valsartan API and valsartan drug product, and if 3 that's what we are talking about, Mr. Stanoch, there 4 are no tests for nitrosamine in those monographs. 5 Q. That would be for both the branded Diovan 6 product as well as generic valsartan products, 7 correct? 8 A. I think you are saying that correctly, 9 Mr. Stanoch, that USP doesn't distinguish between 10 manufacturers. The monographs are supposed to apply 11 to all manufacturers of the named article. 12 Q. When you refer in your report to 13 compendial requirements, what do you mean? 14 A. Well, in brief, I think, as we have 15 already discussed, we're talking about the 16 monographs, in this case, for valsartan drug 17 substance and valsartan drug product. 18 Q. Right. And you have looked at a couple of 19 monographs for valsartan, correct? 20 A. Yes, I think they were part of the 21 information I looked at, and I think they are in my 22 materials considered. And I'm glad to talk about 23 them if you wish, Mr. Stanoch. 24 Q. Of course. Would you agree that 25 compendial requirements includes the general USP</p>	<p style="text-align: right;">Page 128</p> <p>1 February 2021. 2 Q. I apologize. That's correct. I agree 3 with you there. 4 I'm going to mark an exhibit. Stand by, 5 sir. 6 (Whereupon, Exhibit 7 was marked for 7 identification.) 8 BY MR. STANOCH: 9 Q. Stand by. 10 Okay. Exhibit 7, sir, has now been 11 marked. It also should be Tab 17 in your binder if 12 you would like to look at the hard copy. Tell me 13 when you are there. 14 A. Yes, I'm looking at it, Mr. Stanoch. 15 I'm -- 16 Q. Excellent. And this appears to be a copy 17 of the valsartan USP monograph printed January 28th, 18 2022. Do you see that? 19 A. Yes, and -- okay. Yes, I'm prepared to 20 discuss. 21 Q. Very good. So this would be an example of 22 a USP monograph that we were talking moments ago, 23 correct? 24 A. Exactly. 25 Q. All right. And this monograph is for</p>
<p style="text-align: right;">Page 127</p> <p>1 chapters? 2 A. Yes, the way I would say it is there is 3 general notices, which appear at the front of USP 4 and are generally applicable, and then a monograph 5 can reference general chapters that give detailed 6 information about a particular test or procedure. 7 Q. Got it. So it's fair to say, then, that 8 compendial requirements includes a drug monograph, 9 general notices and requirements, and conformance to 10 standards? 11 A. Yes. And if a monograph references a 12 general chapter, that would be part of the 13 monograph. 14 Q. And those also would include notices on 15 impurities, correct? 16 A. My sense is that impurities are a 17 universal test and should be present in most, if not 18 all, drug-substance and drug-product monographs, and 19 that would certainly be true of the valsartan 20 monographs. 21 Q. Uh-huh, uh-huh. And we talked earlier 22 that the FDA nitrosamine impurities guidance, I 23 think you said, was updated last September 2021? 24 A. Well, it appeared first in draft in 25 September '20, and then it was updated in</p>	<p style="text-align: right;">Page 129</p> <p>1 valsartan, correct? 2 A. Yes. 3 Q. And the date of this is current official 4 from last month, so this was after the FDA's last 5 turn of its nitrosamine impurities guidance in 6 February 2021, right? 7 A. I'm not sure I understood what you said. 8 It says, "Official Date: Official as of" May 1, 9 2020. Are we looking at the same thing? 10 Q. Right. And "Official Status" right above 11 that, sir, "Official Status: Currently Official on 12 28-Jan-2022." You see that? 13 A. I do, and that would be about a year after 14 the nitrosamine guidance. 15 Q. I can agree with that. And do you see any 16 mention of a test for nitrosamines in this valsartan 17 monograph? 18 A. All right. Now hold on just a sec. Okay. 19 When we get to "Impurities," I see, "Procedure 1: 20 Limit of Valsartan Related Compound A." "Procedure 21 2: Limit of Valsartan Related Compound B, Valsartan 22 Related Compound C, and Other Related Compounds." 23 And that's all I see. I do not see tests for 24 nitrosamine impurities. 25 Q. Do you see any reference to acceptable</p>

<p style="text-align: right;">Page 130</p> <p>1 limits for nitrosamines in this monograph?</p> <p>2 A. I do not.</p> <p>3 Q. Do you see any mention whatsoever of</p> <p>4 nitrosamines in this valsartan monograph?</p> <p>5 A. I don't believe -- I do not, Mr. Stanoch.</p> <p>6 Please correct me if you think I'm wrong.</p> <p>7 Q. No, I think you are correct. I just</p> <p>8 wanted to make sure we're on the same page. I don't</p> <p>9 see any mention of nitrosamines whatsoever in this</p> <p>10 monograph, and it sounds like you agree with me,</p> <p>11 correct?</p> <p>12 A. Yes.</p> <p>13 Q. So if a drug manufacturer made valsartan</p> <p>14 exactly per this monograph, they wouldn't</p> <p>15 necessarily be doing anything to test or control for</p> <p>16 NDMA, would they?</p> <p>17 A. If they just followed the monograph, I</p> <p>18 think I would agree with you.</p> <p>19 Q. Right. Following a monograph alone would</p> <p>20 not mean that a product was complying with the FDA's</p> <p>21 nitrosamine impurity guidance and limits, correct?</p> <p>22 A. Oh, I'm sorry. I'm hesitating a little</p> <p>23 bit because you alluded back to the nitrosamine</p> <p>24 impurities guidance.</p> <p>25 Q. Well, I'll withdraw the question and I'll</p>	<p style="text-align: right;">Page 132</p> <p>1 that specifically applies to a genotoxic impurity</p> <p>2 such as nitrosamines.</p> <p>3 Q. Uh-huh. Uh-huh. As of the date of this</p> <p>4 valsartan monograph, January 28, 2022, if a</p> <p>5 manufacturer followed it exactly, it would have no</p> <p>6 way of testing and identifying nitrosamines in the</p> <p>7 product, correct?</p> <p>8 MS. LOCKARD: Objection. Vague.</p> <p>9 THE WITNESS: I think I'll agree with you,</p> <p>10 Mr. Stanoch.</p> <p>11 BY MR. STANOCH:</p> <p>12 Q. So whether a product was made according to</p> <p>13 a USP monograph or not does not definitively speak</p> <p>14 to whether the product contains nitrosamines,</p> <p>15 correct?</p> <p>16 A. Well, remember, you don't make a product</p> <p>17 according to a monograph. This is a monograph that</p> <p>18 has tests, procedures, acceptance criteria, that if</p> <p>19 you -- I'm trying to get into the USP</p> <p>20 understanding -- if your drug substance conforms to</p> <p>21 all these tests, then you can confirm that you have</p> <p>22 valsartan.</p> <p>23 Now, as you are discussing, and I agree</p> <p>24 with you, it doesn't say, does your valsartan have</p> <p>25 nitrosamine impurities that are adequately</p>
<p style="text-align: right;">Page 131</p> <p>1 phrase it again. Following this monograph alone to</p> <p>2 manufacture valsartan would not have any specified</p> <p>3 way of identifying and controlling nitrosamines,</p> <p>4 correct?</p> <p>5 A. I think you are -- yes, I agree with you,</p> <p>6 Mr. Stanoch.</p> <p>7 Q. Uh-huh. So the fact that a drug complies</p> <p>8 with a USP monograph alone does not mean the drug is</p> <p>9 free of any nitrosamine impurities?</p> <p>10 A. Yes, I think you are right. That ability</p> <p>11 to control nitrosamine would come up in the</p> <p>12 application to FDA and the FDA review. It would not</p> <p>13 be in the USP monograph.</p> <p>14 Q. Okay. And the USP is not responsible for</p> <p>15 identifying genotoxic impurities in drug product or</p> <p>16 drug substance, right?</p> <p>17 A. No, I agree with your -- that to me is</p> <p>18 more a regulatory matter.</p> <p>19 Q. All right. USP believes companies are</p> <p>20 responsible for identifying and assessing genotoxic</p> <p>21 impurities in their drug product or substance,</p> <p>22 correct?</p> <p>23 A. Yes. It's up to the manufacturer working</p> <p>24 with FDA to detect -- I'm trying to think of the</p> <p>25 string of words -- report, identify, qualify, and</p>	<p style="text-align: right;">Page 133</p> <p>1 controlled? That is a separate matter that is</p> <p>2 adjudicated by FDA.</p> <p>3 Q. Uh-huh. And USP general notices and</p> <p>4 requirements may also guide a manufacturer on how to</p> <p>5 identify nitrosamine impurities, correct?</p> <p>6 A. Well, yeah, there may be some statements</p> <p>7 in there that are very general statements, for</p> <p>8 example, that you have to follow GMPs, and GMPs may</p> <p>9 say, yes, you have to think about a genotoxic</p> <p>10 impurity.</p> <p>11 And I have heard it said, although I</p> <p>12 haven't seen it, Mr. Stanoch, I have heard that USP</p> <p>13 has general chapters on how to measure nitrosamine</p> <p>14 impurities.</p> <p>15 Q. Uh-huh.</p> <p>16 A. But I can't confirm that. I just heard</p> <p>17 it. Maybe you are aware of it and I'm not.</p> <p>18 Q. And is that discussed anywhere in your</p> <p>19 report, sir?</p> <p>20 A. No, not at all. And as a matter of fact,</p> <p>21 this monograph is not discussed in my report. I</p> <p>22 think I am talking about monographs that were</p> <p>23 official at the time of the 2018 time period.</p> <p>24 Q. So, well, we can pull those up too,</p> <p>25 Doctor. But if someone followed the USP monograph</p>

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1 for valsartan products in the 2018 time period, so
 2 too they would have nothing from the monograph
 3 itself about identifying nitrosamines, correct?
 4 A. Yes. I agree with that, Mr. Stanoch.
 5 Q. Uh-huh. That does not mean, though, that
 6 the drug ultimately might not contain any
 7 nitrosamines, right?
 8 A. Or that they might be controlled in
 9 another way.
 10 Q. Correct. And it may be that even if a
 11 valsartan product was made according to the 2018
 12 monograph, that the drug could still be adulterated
 13 under FDA regulations?
 14 MS. LOCKARD: Objection. Vague.
 15 Speculation.
 16 THE WITNESS: I'm struggling a little bit
 17 with what you said. Now, if you are citing the act,
 18 I think we would say it was not adulterated
 19 according to the provisions of the act that talk
 20 about a USP standard, but it could be adulterated
 21 under a private specification, which is allowed in
 22 the act in the citation I provided.
 23 BY MR. STANOCH:
 24 Q. Uh-huh.
 25 A. Or it could be part of a GMP violation.

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1 Q. Let's take examples of some other drugs,
 2 Dr. Williams. Let's take an example of a drug that
 3 was made according to USP compendial standards. You
 4 with me so far?
 5 A. I'm a little hesitant to talk about making
 6 a drug according to the standards because USP does
 7 not give process steps. So you might make a drug
 8 according to your process steps and then test it
 9 according to a USP monograph.
 10 Q. Uh-huh. Well, that's a fair point,
 11 Doctor, that a manufacturer's individual process may
 12 have issues arise through it that are not covered by
 13 the monograph itself.
 14 A. Yes, exactly.
 15 Q. Right. And it would be incumbent on the
 16 manufacturer to understand its own individual
 17 process and to assess the potential for any
 18 impurities in the product even if the manufacturer
 19 is otherwise following the monograph, right?
 20 A. I agree with the way you stated that.
 21 Thank you.
 22 Q. Okay. And so let me go back to my
 23 example. I'll try to think -- I'll try to phrase it
 24 more accurately for you.
 25 Let's take a drug that met all compendial

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1 requirements. Is that okay?
 2 A. Okay.
 3 Q. Is that an accurate articulation of a
 4 product, that it can meet compendial requirements?
 5 A. It seems to me you are making a statement
 6 about a hypothetical, and I don't disagree with your
 7 hypothetical.
 8 Q. Okay. So let's say there is a drug that
 9 meets all compendial requirements, but it contains
 10 anthrax. Is that drug adulterated?
 11 MS. LOCKARD: Objection. Speculation.
 12 MR. STANOCH: I can ask a hypothetical,
 13 Counsel.
 14 Q. Go ahead, Dr. Williams.
 15 MS. LOCKARD: Incomplete hypothetical.
 16 Objection.
 17 THE WITNESS: You know, it's a
 18 hypothetical, and I would say, yes, it's got an
 19 unacceptable contaminant.
 20 BY MR. STANOCH:
 21 Q. Let's say a different, slightly different
 22 hypothetical. Say a drug met all compendial
 23 requirements but there was rat poison in it. Can it
 24 be adulterated?
 25 MS. LOCKARD: Objection. Calls for

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1 speculation. Incomplete hypothetical.
 2 THE WITNESS: Again, I would say it has a
 3 unacceptable contaminant.
 4 BY MR. STANOCH:
 5 Q. Even though the compendial requirements
 6 may not have a test for rat poison, correct?
 7 A. Exactly.
 8 Q. Uh-huh. And let's take another example.
 9 Let's say there is a drug that met all compendial
 10 requirements, but broken glass are in the capsules.
 11 Could it be adulterated?
 12 MS. LOCKARD: Objection. Speculation.
 13 Incomplete hypothetical.
 14 THE WITNESS: Well, it could be
 15 adulterated according to GMPs, but I think it could
 16 not be adulterated according to the compendial
 17 standard in the act.
 18 I have got another good example, which is
 19 the tampering of the Tylenol many years ago where
 20 somebody put needles in the bottles. I don't know
 21 if you remember that, Mr. Stanoch. Do you recall
 22 that?
 23 BY MR. STANOCH:
 24 Q. No, I don't.
 25 A. Well, FDA went to great trouble working

<p style="text-align: right;">Page 138</p> <p>1 with a highly responsible manufacturer to get that 2 product off the shelves. 3 Q. And was that product considered 4 adulterated because of the presence of needles in 5 the bottles? 6 A. I think you could probably say that it was 7 a GMP failure of some kind, but -- 8 Q. Uh-huh. 9 A. At a certain point in time, FDA could take 10 action, you know, as it deems appropriate for public 11 health. 12 Q. Uh-huh. And in your example of the 13 Tylenols with needles in the bottle, did a consumer 14 who got a bottle with a needle in it before any FDA 15 action, were they holding an adulterated product? 16 A. I can't remember the details. I think you 17 are asking sort of a speculative question. I think 18 you could say it was adulterated because of failure 19 of GMPs. 20 Q. But you could -- 21 A. You know, FDA has broad authority to 22 remove adulterated products from the market. I can 23 say that. 24 Q. Sure. I would agree with that. But you 25 can have a product, in this example we're talking</p>	<p style="text-align: right;">Page 140</p> <p>1 what is there according to tests, procedures, and 2 acceptance criteria. It couldn't possibly assess 3 all the possible negative things that might be 4 there. 5 Q. Right. And in this example, assuming you 6 have a product that met all compendial requirements 7 except it also contained anthrax, the consumer 8 holding that product is holding an adulterated 9 product prior to any FDA action against that 10 manufacturer, fair? 11 A. Yes. And as long as we're staying with 12 these hypotheticals, I can say a valsartan monograph 13 could have an impurity procedure for nitrosamines. 14 Of course, it would take very specialized equipment, 15 and it might have the limits set by FDA via the 16 guidance. So there is nothing precluding that. 17 Q. So -- 18 A. And I'm not exactly sure why it hasn't 19 occurred, but maybe companies are figuring out a way 20 to keep their manufacturing process such that the 21 limits are met without testing. 22 Q. Okay. And you have not seen any USP 23 monograph for valsartan that contains any impurity 24 procedures for nitrosamines, right? 25 A. I have not.</p>
<p style="text-align: right;">Page 139</p> <p>1 about, the consumer's holding a bottle of Tylenol 2 with needles in it. That product they are holding 3 is adulterated even prior to an FDA action against 4 the manufacturer, is it not? 5 A. I think you could say that. I think 6 people wouldn't quibble with that designation. 7 Q. Okay. You can say the same with sort of 8 the other examples. For example, I mean, we talked 9 about a drug made to compendial requirements that 10 contained anthrax. That drug in a consumer's hand 11 would be adulterated prior to the FDA taking 12 official action against the manufacturer, correct? 13 MS. LOCKARD: Objection. Speculation. 14 Incomplete hypothetical. 15 THE WITNESS: Yeah, I -- I'm sorry. I 16 have lost track of your question. The hypothetical 17 that the product has been willfully adulterated? 18 BY MR. STANOCH: 19 Q. The question simply was another example. 20 I'll say it again. Assume you have a product that 21 met all compendial requirements, except it also 22 contained anthrax. You with me? 23 A. Yes. I think you are making general 24 statements that are quite true, Mr. Stanoch, that 25 the compendial standard really is designed to assess</p>	<p style="text-align: right;">Page 141</p> <p>1 Q. Uh-huh. 2 MS. LOCKARD: We have been going about an 3 hour since the last break, so whenever you get to a 4 stopping point, I would like a break. 5 MR. STANOCH: Now is fine. 6 Doctor, would you like to take a break? 7 THE WITNESS: That would be nice, 8 Mr. Stanoch. Thank you. 9 MR. STANOCH: Let's do it. Great. 10 THE VIDEOGRAPHER: Great. Then we are 11 going off the record. The time is 10:49. 12 (Whereupon, a brief recess was taken.) 13 THE VIDEOGRAPHER: Okay. We are coming 14 back on the record. The time on the video monitor 15 is 11:07. Please begin. 16 BY MR. STANOCH: 17 Q. Welcome back, Dr. Williams. 18 A. Hi, Mr. Stanoch. 19 Q. Did you talk with anyone besides your 20 counsel during the break? 21 A. No, I did not. 22 Q. Did you talk with your counsel during the 23 break? 24 A. Yes, I did. 25 Q. And did you look at any documents during</p>

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1 the break?

2 A. We sort of looked through the documents in

3 the binder you provided, but we didn't review any.

4 And we didn't get through all the documents. There

5 were a few at the end we didn't look at, at all.

6 Q. You flipped through the binder of

7 potential exhibits?

8 A. Yes.

9 MS. LOCKARD: Just very briefly.

10 MR. STANOCH: Counsel, I'm going to --

11 MS. LOCKARD: We didn't go through these

12 documents.

13 MR. STANOCH: Counsel, and I didn't think

14 I needed to state this, but I'll put on the record,

15 I object to you flipping through the courtesy binder

16 of potential exhibits we prepared at your request

17 for the convenience of the witness.

18 Not all of them may be used. We want them

19 not to be looked at, certainly to be destroyed

20 without looking at them, the witness or counsel,

21 especially when we're doing it as a courtesy to you

22 and the witness, when we have asked for similar

23 courtesies from your side, not you, Counsel, but

24 other counsel on your side, we have been flat-out

25 rejected when we have asked for hard copies.

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1 So it's very troubling to me that you are

2 looking through all potential exhibits we provided,

3 and I would ask that that not happen again, now or

4 at a future deposition.

5 MS. LOCKARD: As the witness said, we did

6 not discuss these documents. I'm trying to make

7 sure I have copies of them in hand. We have one

8 binder here that I'm having to walk over and look

9 over Dr. Williams' shoulder, so --

10 MR. STANOCH: Every single document I

11 marked from the binder, Counsel, is also put up on

12 the screen for all counsel on the Zoom to see. So I

13 would just ask that no one looks at the binder until

14 the witness is directed to do it. Thank you.

15 MS. LOCKARD: Well, I would like to have

16 hard copies in my hand because on some of these we

17 don't even have the full document up on the screen,

18 just showing pages.

19 MR. STANOCH: Well, first of all, that

20 wasn't the request. It was for your witness.

21 Second of all, when we have asked for the

22 same thing for our witness, let alone us, we have

23 been flat-out refused by some on your side, not you.

24 So going forward, we can talk about this, but again,

25 for now I'm asking, do not look at the binder until

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1 an exhibit is marked. Thank you.

2 MS. LOCKARD: That's fine. You may have

3 to give me a moment to find the document in hard

4 copy if I need to. So --

5 BY MR. STANOCH:

6 Q. Did you look at any other documents,

7 Doctor, during the break?

8 A. No, no other documents.

9 Q. Okay. Doctor, would you agree that if a

10 manufacturer controls impurities and degradation

11 products in accordance with only a pharmacopeial

12 monograph, that is acceptable to regulators?

13 A. I think it can be, yes. If it is a good

14 monograph, it can be sufficient to control the

15 product in the marketplace.

16 Q. What if the individual monograph is

17 inadequate to control an impurity?

18 A. If we're talking about the nitrosamine, I

19 would say then there needs to be additional

20 requirements that are private, agreed to with FDA.

21 Q. Uh-huh. Well, what agreements with FDA

22 does any valsartan manufacturer have today, given

23 that we looked at the valsartan monograph and there

24 is nothing about nitrosamines in it?

25 A. Well, I can only speak to Teva, and the

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1 answer to that is clear, there are no Teva valsartan

2 products in the U.S. marketplace. As we have

3 already discussed, Teva immediately recalled them --

4 "immediately" can be a little debatable -- when the

5 impurities were discovered.

6 Q. Uh-huh. Is it incumbent on the

7 manufacturer that discovers an impurity to develop

8 and validate appropriate analytical procedures,

9 establish acceptance criteria, and communicate with

10 USP?

11 A. There is no obligation for a manufacturer

12 to work with USP at all. That's voluntary.

13 Q. Uh-huh.

14 A. I would say there is a requirement to do

15 so with FDA if you come to the private

16 specification.

17 Q. I'm going to mark the next exhibit. Stand

18 by.

19 (Whereupon, Exhibit 8 was marked for

20 identification.)

21 BY MR. STANOCH:

22 Q. I have marked Exhibit 8, Doctor, it's

23 actually Tab 12 in your -- tell me when you're

24 there, sir.

25 (Reporter clarification.)

<p style="text-align: right;">Page 146</p> <p>1 BY MR. STANOCH:</p> <p>2 Q. Binder. Tell me when you are there.</p> <p>3 A. Okay. I have been handed Tab 12, which</p> <p>4 looks like it's about 20 or 30 pages of a USP</p> <p>5 webcast. So I'm there, Mr. Stanoch.</p> <p>6 Q. Very good. And this is a USP presentation</p> <p>7 entitled "Impurities in Drug Products and Drug</p> <p>8 Substances - A USP Approach," yes?</p> <p>9 A. Yes.</p> <p>10 Q. And you see the last update on the first</p> <p>11 page is March 2018, right?</p> <p>12 A. Wait a minute. I'm trying to find</p> <p>13 March 2018. Where is that?</p> <p>14 Q. Slide 1, lower left, light gray text.</p> <p>15 A. Yes, it's very faint in my print, but yes,</p> <p>16 I can see it. Thank you, Mr. Stanoch.</p> <p>17 Q. Not a problem. It's faint in mine too and</p> <p>18 in the original. That's why I was happy to draw</p> <p>19 your attention to it.</p> <p>20 So this is prior to the valsartan recalls</p> <p>21 that began in the summer of 2018, right?</p> <p>22 A. March 2018. Okay. I'm with you. Yes.</p> <p>23 Thank you. I agree.</p> <p>24 Q. Good. Let's flip to Slide 36. So if you</p> <p>25 are looking at the little page numbers in the lower</p>	<p style="text-align: right;">Page 148</p> <p>1 may lead to different impurities."</p> <p>2 Did I read that right?</p> <p>3 A. Yes, you read that correctly.</p> <p>4 Q. Do you agree with that statement?</p> <p>5 A. I do agree with it.</p> <p>6 Q. Then it also reads, "If an individual</p> <p>7 monograph is inadequate to control an impurity, the</p> <p>8 manufacturer is responsible for developing and</p> <p>9 validating appropriate analytical procedures,</p> <p>10 establishing acceptance criteria, and communicating</p> <p>11 with USP."</p> <p>12 Did I read that right?</p> <p>13 A. Yes, you did. And I agree with that</p> <p>14 statement.</p> <p>15 Q. Okay. So what USP is advising in this</p> <p>16 slide is that it's -- the onus on the manufacturer</p> <p>17 to understand and evaluate its own process and any</p> <p>18 impurities that may arise in that process for a</p> <p>19 drug, correct?</p> <p>20 A. Yes, I think you are stating it correctly.</p> <p>21 Q. Uh-huh. If you can flip to the slide --</p> <p>22 page 63. Let me know when you are there.</p> <p>23 A. Okay. I'm on page 63, top of the page.</p> <p>24 Q. Great. And it says, "Setting Acceptance</p> <p>25 Criteria for Impurities," right?</p>
<p style="text-align: right;">Page 147</p> <p>1 right, it would be the page that has Slides 35 and</p> <p>2 36 on it.</p> <p>3 A. 34. So I am looking at 35 and 36. Yes,</p> <p>4 I'm there.</p> <p>5 Q. Okay. You see there is a Q and A on Slide</p> <p>6 36, correct?</p> <p>7 A. I do see that.</p> <p>8 Q. And the question is: "If a manufacturer</p> <p>9 controls impurities and degradation products in</p> <p>10 accordance with only a pharmacopeial monograph, is</p> <p>11 that acceptable to the regulators?" Did I read that</p> <p>12 right?</p> <p>13 A. Yes, you did.</p> <p>14 Q. Then there is a three-bullet answer,</p> <p>15 correct?</p> <p>16 A. Yes, I do see that.</p> <p>17 Q. Okay. And it notes first the monographs</p> <p>18 are based on historic preparation, right?</p> <p>19 A. Yes. I'm not exactly sure what that</p> <p>20 means, but you are reading it correctly.</p> <p>21 Q. And then the next bullet notes that, "A</p> <p>22 particular manufacturer's manufacturing method for</p> <p>23 formulation components may lead to unexpected</p> <p>24 impurities, due to a different route of synthesis,</p> <p>25 different reagents, et cetera. Different processes</p>	<p style="text-align: right;">Page 149</p> <p>1 A. Yes.</p> <p>2 Q. And there is three bullets there?</p> <p>3 A. Yes, I see that.</p> <p>4 Q. Let me direct your attention to the third</p> <p>5 bullet. Are you there?</p> <p>6 A. Yes.</p> <p>7 Q. And read the first sentence for us.</p> <p>8 A. "If a limit for a specified impurity does</p> <p>9 not exist in the USP, FDA recommends that you</p> <p>10 qualify the impurity by comparing it to the observed</p> <p>11 amounts of the impurity in the reference listed</p> <p>12 drug. Your acceptance criterion should be similar</p> <p>13 to the level observed in the" reference listed drug.</p> <p>14 "Alternatively, the acceptance criteria may be set</p> <p>15 based on a qualified level that is justified by</p> <p>16 scientific literature, metabolite data, or toxicity</p> <p>17 studies."</p> <p>18 Q. Do you agree with that statement?</p> <p>19 A. I do.</p> <p>20 Q. Uh-huh. So the event that, say, a</p> <p>21 valsartan USP monograph did not contain a limit for</p> <p>22 a nitrosamine, the recommendation would be for the</p> <p>23 manufacturer to qualify the impurity, correct?</p> <p>24 A. If the impurity existed in their product,</p> <p>25 I think you could make that claim.</p>

<p style="text-align: right;">Page 150</p> <p>1 Q. Do you know if, prior to the summer of 2 2018, Teva ever made any effort to qualify any 3 nitrosamine impurity in its valsartan products? 4 A. I think they did not. They did not 5 suspect them, and their analytical tests in their 6 private or public specification wouldn't have picked 7 up a nitrosamine impurity. 8 Q. Uh-huh. Again, though, you don't know 9 like what tests Teva in particular might have been 10 employing for valsartan at the time, right? 11 A. Well, it seems to me we could assume they 12 were following the USP monograph for valsartan -- 13 Q. Uh-huh. 14 A. -- and valsartan drug product. 15 Q. Uh-huh. But you don't know how Novartis 16 was able to detect NDMA in valsartan API whereas 17 Teva did not? 18 MS. LOCKARD: Objection. Asked and 19 answered. 20 THE WITNESS: Yeah, that is sort of a 21 different set of questions. And Novartis would have 22 been following the monograph, too, for valsartan and 23 valsartan drug product if it existed. 24 BY MR. STANOCH: 25 Q. Well, that's sort of the point, Doctor,</p>	<p style="text-align: right;">Page 152</p> <p>1 wanted on another product for a myriad of reasons, 2 but I just don't have any information about what 3 Novartis was doing with the ZHP product. 4 BY MR. STANOCH: 5 Q. You look on the next page, on 65, sir. 6 Tell me when you are there. 7 A. Yes. Top of the page? 8 Q. Yes. It reads, "USP General Chapters for 9 Impurities: <476> & <1086>?" 10 A. Yes, I do see that. 11 Q. And these are examples of general chapters 12 in the USP that would be part of so-called 13 compendial requirements, correct? 14 A. Yes. I think we have alluded to this 15 before in our prior discussion. 16 Q. Thank you. You can put that aside for 17 now. 18 I'm going to mark the next exhibit. Stand 19 by, sir. 20 (Whereupon, Exhibit 9 was marked for 21 identification.) 22 BY MR. STANOCH: 23 Q. This will be Exhibit 9. It's Tab 13 in 24 your binder, sir. Tell me when you are there. 25 A. Okay. I'm seeing it. It, again, is a USP</p>
<p style="text-align: right;">Page 151</p> <p>1 that Novartis, following the monograph that did not 2 contain any mention of nitrosamines, nonetheless did 3 a test that detected the nitrosamines, right? 4 MS. LOCKARD: Objection. Lacks 5 foundation. Speculation. Outside the scope of his 6 opinions. 7 THE WITNESS: Yeah, I have already stated, 8 Mr. Stanoch, I have no understanding of what 9 Novartis was doing. 10 BY MR. STANOCH: 11 Q. Would you agree, though, that Novartis 12 performed some test that was not in the monograph 13 that detected the nitrosamines, correct? 14 MS. LOCKARD: Objection. Speculation. 15 Lacks foundation. Outside of his opinions in the 16 class-certification report. 17 THE WITNESS: I think what I was trying to 18 say is that when Novartis released its Diovan into 19 the U.S. market, it would try to make sure it 20 conformed to the USP valsartan and valsartan 21 drug-product monographs. Those monographs, as I 22 have already said, apply to brand and generic 23 manufacturers. 24 Now, speaking hypothetically, any company, 25 including Novartis, could do any kind of testing it</p>	<p style="text-align: right;">Page 153</p> <p>1 document. 2 Q. Correct. 3 A. "Overview of" -- "General Chapters <476> 4 and <1086>." 5 Q. Yes, sir. And the date on that document? 6 A. Another visual acuity test. I don't 7 see -- 8 Q. I see October 19th, 2017, right on the 9 title page. 10 A. Oh, right, yeah. Right. Thank you. 11 Q. Is that right? 12 A. Yes, exactly, thank you. 13 Q. Oh, good. No problem. And have you seen 14 this -- actually -- strike that. 15 Have you seen the last exhibit prior to 16 today, sir? 17 A. No, I haven't, nor this one. 18 Q. Thank you. Okay. So let's flip to page 19 13, sir. Tell me when you are there. 20 A. And where will I see the page numbers? 21 Q. Oh, it's the lower right of the pages. 22 The title is, "Manufacturers responsibilities in 23 <1086> and <476>." 24 A. Okay. I'm there. I see it. 25 Q. Okay. In this slide in the USP</p>

<p style="text-align: right;">Page 154</p> <p>1 presentation, sets forth what it says are</p> <p>2 "Manufacturer's Responsibilities in General Chapter</p> <p>3 <1086>" and "Manufacturer's Responsibilities in</p> <p>4 General Chapter <476>." Do you see that?</p> <p>5 A. I do see that.</p> <p>6 Q. And then why don't you read that first</p> <p>7 bullet that begins, "If a new impurity"?</p> <p>8 A. "If a new impurity is detected above the</p> <p>9 appropriate identification threshold or when the</p> <p>10 level of a specified related compound increases as</p> <p>11 compared to its characteristic impurity profile, the</p> <p>12 manufacturer is responsible for evaluating the</p> <p>13 impact on the safety and efficacy of the drug</p> <p>14 substance or drug product."</p> <p>15 Shall I continue?</p> <p>16 Q. Do you agree with that -- no, why don't</p> <p>17 you -- just that bullet. Do you agree with that</p> <p>18 statement, sir?</p> <p>19 A. Yes, I do.</p> <p>20 Q. Okay. Why don't you read the second</p> <p>21 bullet.</p> <p>22 A. "For marketed products, the manufacturers</p> <p>23 are responsible for controlling organic impurities</p> <p>24 in accordance with current regulatory standards."</p> <p>25 Q. Do you agree with that statement, sir?</p>	<p style="text-align: right;">Page 156</p> <p>1 that statement you just read. Do you agree with</p> <p>2 that statement, sir?</p> <p>3 A. I do agree with it.</p> <p>4 Q. And could you read the final bullet, sir?</p> <p>5 A. Right. "Manufacturers shall develop</p> <p>6 acceptance criteria for impurities justified by</p> <p>7 appropriate safety considerations and consistent</p> <p>8 with current applicable regulatory guidances."</p> <p>9 Q. Do you agree with that statement as well,</p> <p>10 sir?</p> <p>11 A. I do.</p> <p>12 Q. Okay. Thank you. Let's put that aside</p> <p>13 for now. Stand by for the next exhibit.</p> <p>14 (Whereupon, Exhibit 10 was marked for</p> <p>15 identification.)</p> <p>16 BY MR. STANOCH:</p> <p>17 Q. I am marking Exhibit 10. Sir, that should</p> <p>18 be Tab 14 in your binder. Let me know when you are</p> <p>19 there.</p> <p>20 A. Yes, I'm there.</p> <p>21 Q. Okay. This is a slide deck from the FDA.</p> <p>22 You see that, sir?</p> <p>23 A. I do. Dated October 2, 2020.</p> <p>24 Q. Correct. And you see the two names of the</p> <p>25 presenters there, Dr. -- is it Keire and Dr. Lu?</p>
<p style="text-align: right;">Page 155</p> <p>1 A. I do.</p> <p>2 Q. Could you read the next one under the</p> <p>3 subheading "Manufacturer's Responsibilities in</p> <p>4 General Chapter <476>"?</p> <p>5 A. The first bullet?</p> <p>6 Q. Yes, sir.</p> <p>7 A. "If an individual monograph is inadequate</p> <p>8 to control does not include a procedure for</p> <p>9 qualifying an impurity or acceptance criterion for</p> <p>10 an observed impurity, the manufacturer is</p> <p>11 responsible for developing and validating</p> <p>12 appropriate analytical procedures and establishing</p> <p>13 appropriate acceptance criteria."</p> <p>14 Q. Do you agree with that statement, sir?</p> <p>15 A. Yes, it seems -- I can agree with it.</p> <p>16 Q. Could you kindly read the next one, sir?</p> <p>17 A. "Manufacturers shall validate or verify,</p> <p>18 as appropriate analytical procedures must</p> <p>19 demonstrate their suitability for detection and</p> <p>20 quantification of impurities in the drug substances</p> <p>21 and drug products."</p> <p>22 Q. Thank you.</p> <p>23 A. "Manufacturers shall develop" -- oh, I'm</p> <p>24 sorry. I went on.</p> <p>25 Q. That's fine. Let's just stop there at</p>	<p style="text-align: right;">Page 157</p> <p>1 A. I do see those names.</p> <p>2 Q. Did you work with them when you were at</p> <p>3 the FDA?</p> <p>4 A. I don't recognize these names.</p> <p>5 Q. Quite all right. And have you seen this</p> <p>6 slide presentation before, sir?</p> <p>7 A. No, I haven't.</p> <p>8 Q. Let's turn to page 3. Tell me when you</p> <p>9 are there.</p> <p>10 A. Is this the one that states,</p> <p>11 "Pharmaceutical Quality"?</p> <p>12 Q. Yes, sir.</p> <p>13 A. Yes, I'm there.</p> <p>14 Q. It states, "A quality product of any kind</p> <p>15 consistently meets the expectations of the user,"</p> <p>16 correct?</p> <p>17 A. Yes, I see that.</p> <p>18 Q. And then flip to the next slide. You</p> <p>19 there?</p> <p>20 A. Yes.</p> <p>21 Q. Now it says, "A quality product of any</p> <p>22 kind consistently meets the expectations of the</p> <p>23 user. Drugs are no different," correct?</p> <p>24 A. I see that.</p> <p>25 Q. Do you agree with that characterization of</p>

<p style="text-align: right;">Page 158</p> <p>1 pharmaceutical quality?</p> <p>2 MS. LOCKARD: Objection. Outside the</p> <p>3 scope of his class-certification opinions. Vague.</p> <p>4 THE WITNESS: I don't want to debate what</p> <p>5 the FDA is saying here, but I will say that users,</p> <p>6 sometimes including me, can be very uninformed about</p> <p>7 what the expectation for a product should be. But I</p> <p>8 don't want to debate it. You know, I certainly can</p> <p>9 agree with it generally.</p> <p>10 BY MR. STANOCH:</p> <p>11 Q. Understood. And would you agree, though,</p> <p>12 that users of a drug have no way of knowing if the</p> <p>13 drug contains nitrosamines absent the disclosure by</p> <p>14 the manufacturer or regulator?</p> <p>15 MS. LOCKARD: Objection. Speculation.</p> <p>16 Vague.</p> <p>17 THE WITNESS: Yes, some kind of</p> <p>18 disclosure. And I think you were more specific</p> <p>19 about what I was trying to say. It's very hard for</p> <p>20 a user to understand what the quality expectations</p> <p>21 of a medicine are.</p> <p>22 BY MR. STANOCH:</p> <p>23 Q. Uh-huh. And you can flip to the next page</p> <p>24 of the slide, sir.</p> <p>25 A. "Patients expect safe and effective"?</p>	<p style="text-align: right;">Page 160</p> <p>1 sir. You can tell me when you are there.</p> <p>2 A. Oh, wait. Okay. Yes, I'm on 9.</p> <p>3 Q. And here we see reference to the ICH M7</p> <p>4 guidance again?</p> <p>5 A. Yes, I do. Yes, exactly.</p> <p>6 Q. And again, there is reference to the</p> <p>7 nitroso compounds being part of a cohort of concern,</p> <p>8 right?</p> <p>9 A. Yes, I see that.</p> <p>10 Q. I think we established earlier, but you</p> <p>11 can correct me if I'm wrong, that we agree that the</p> <p>12 ICH M7 includes nitroso compounds in the so-called</p> <p>13 cohort of concern, right?</p> <p>14 MS. LOCKARD: Objection. Asked and</p> <p>15 answered. Outside the scope of his deposition.</p> <p>16 THE WITNESS: Yes. And this is a very</p> <p>17 general statement, but I see nothing to disagree</p> <p>18 with.</p> <p>19 BY MR. STANOCH:</p> <p>20 Q. Go back to the slide we were looking at</p> <p>21 prior to this, the pharmaceutical quality slide.</p> <p>22 A. "Pharmaceutical quality is assuring every</p> <p>23 dose"?</p> <p>24 Q. Yes, sir.</p> <p>25 A. I'm there, Mr. Stanoch.</p>
<p style="text-align: right;">Page 159</p> <p>1 Q. Yes. Just read the sentence for me.</p> <p>2 A. "Patients expect safe and effective</p> <p>3 medicines with every dose they take."</p> <p>4 Q. As a general matter do you agree with</p> <p>5 that?</p> <p>6 MS. LOCKARD: Objection. Calls for</p> <p>7 speculation. Vague.</p> <p>8 THE WITNESS: Yeah, and it's very hard for</p> <p>9 me to know what patients really expect, but I</p> <p>10 certainly don't disagree generally with the</p> <p>11 statement.</p> <p>12 BY MR. STANOCH:</p> <p>13 Q. Uh-huh. And then let's flip to the next</p> <p>14 page, sir.</p> <p>15 A. "Assuring every dose is safe"?</p> <p>16 Q. Yeah. Why don't you just read that whole</p> <p>17 statement there on the slide?</p> <p>18 A. "Pharmaceutical quality is assuring every</p> <p>19 dose is safe and effective, free of contamination</p> <p>20 and defects."</p> <p>21 Q. Uh-huh. Do you generally agree with that</p> <p>22 statement?</p> <p>23 A. Yeah, I don't see anything specifically</p> <p>24 objectionable.</p> <p>25 Q. Uh-huh. And if you can flip to page 9,</p>	<p style="text-align: right;">Page 161</p> <p>1 Q. Very good. Do you believe a valsartan</p> <p>2 drug that contained nitrosamines was safe and</p> <p>3 effective and free of contamination and defects?</p> <p>4 MS. LOCKARD: Objection. Outside the</p> <p>5 scope of his expert opinion for class certification.</p> <p>6 THE WITNESS: I'm sorry. Could you say</p> <p>7 the question again, Mr. Stanoch?</p> <p>8 BY MR. STANOCH:</p> <p>9 Q. Do you believe a valsartan drug that</p> <p>10 contained nitrosamines was safe and effective and</p> <p>11 free of contamination and defects?</p> <p>12 MS. LOCKARD: Same objection. And vague.</p> <p>13 THE WITNESS: Yeah. Speaking separate</p> <p>14 from my report, I think it's possible it could be</p> <p>15 free of contamination and defects, so I guess I'm</p> <p>16 answering yes to your question.</p> <p>17 BY MR. STANOCH:</p> <p>18 Q. And you opine that a, you know, recall is</p> <p>19 taken by companies to remove defective products in</p> <p>20 the market, correct?</p> <p>21 A. Yes. I would say that's the general</p> <p>22 purpose of a recall.</p> <p>23 Q. Uh-huh. Right. And so when Teva</p> <p>24 instituted its recalls for its valsartan products,</p> <p>25 it was removing defective drug product from the</p>

<p style="text-align: right;">Page 162</p> <p>1 market, correct?</p> <p>2 MS. LOCKARD: Objection. Outside the</p> <p>3 scope of his opinion. Also vague and speculation.</p> <p>4 Asking him to give legal opinion.</p> <p>5 BY MR. STANOCH:</p> <p>6 Q. I'm reading from your report, sir. There</p> <p>7 is no speculation.</p> <p>8 A. Yeah, I would say Teva recalled its</p> <p>9 valsartan-containing drug products because of</p> <p>10 nitrosamine contamination.</p> <p>11 Q. Right. And that contamination is what</p> <p>12 rendered them defective, making the voluntary recall</p> <p>13 action appropriate?</p> <p>14 A. Well, but what --</p> <p>15 MS. LOCKARD: Same objections.</p> <p>16 THE WITNESS: The way I would say it, it</p> <p>17 was -- I'm hesitating on the word "contamination."</p> <p>18 The nitrosamines could be there within acceptable</p> <p>19 limits. When -- but working with FDA, Teva recalled</p> <p>20 even though the limits hadn't been set. I'm trying</p> <p>21 to be specific in terms of what my report says.</p> <p>22 BY MR. STANOCH:</p> <p>23 Q. Okay. And so let's slightly rephrase</p> <p>24 that, then, to see if we get on the same page. You</p> <p>25 write -- and you can look at Paragraph 69 of your</p>	<p style="text-align: right;">Page 164</p> <p>1 because of a defective product.</p> <p>2 BY MR. STANOCH:</p> <p>3 Q. And is it your understanding that Teva</p> <p>4 recalled all of its valsartan-containing drug</p> <p>5 products in the summer of 2018?</p> <p>6 A. No. No. I think there was -- the recalls</p> <p>7 in summer of 2018 were for the valsartan drug</p> <p>8 products using ZHP drug substance. And then, based</p> <p>9 on further information that came in over the fall,</p> <p>10 FDA recalled its valsartan drug products containing</p> <p>11 the Mylan product.</p> <p>12 Q. Right. Were you aware that Teva initially</p> <p>13 instituted a hold on the marketing of all its</p> <p>14 valsartan finished-dose products when it heard from</p> <p>15 ZHP in late June 2018?</p> <p>16 A. Yes. I think I am aware of that, and I</p> <p>17 think that's one of the documents -- there are two</p> <p>18 documents I cite in that regard.</p> <p>19 Q. That is correct. And then shortly after</p> <p>20 its hold, Teva lifted its hold on valsartan</p> <p>21 finished-dose made with non-ZHP API, correct?</p> <p>22 A. Yes, I think you are stating it correctly,</p> <p>23 because Teva had no reason to think that it had</p> <p>24 objectionable nitrosamine impurity levels.</p> <p>25 Q. Right. And I'm going to put up a document</p>
<p style="text-align: right;">Page 163</p> <p>1 report if you would like -- "A recall is a voluntary</p> <p>2 action taken by a company to remove a defective drug</p> <p>3 product from the market"; is that right?</p> <p>4 A. All right. I'm going to my report.</p> <p>5 Q. Of course.</p> <p>6 A. Paragraph 69.</p> <p>7 Yes, I'm reading from my report, and I see</p> <p>8 where you are reading, Mr. Stanoch.</p> <p>9 Q. And you characterize elsewhere in your</p> <p>10 report that Teva's recalls of its valsartan products</p> <p>11 were voluntary, that's what you say, right?</p> <p>12 A. Right, right.</p> <p>13 Q. And the defect behind the Teva voluntary</p> <p>14 recalls of its valsartan products were the</p> <p>15 nitrosamine impurities; is that right?</p> <p>16 MS. LOCKARD: Objection. Vague. Outside</p> <p>17 of the scope of his report.</p> <p>18 THE WITNESS: Well, the way I would say it</p> <p>19 is FDA and Teva working together agreed that the</p> <p>20 levels of nitrosamine impurities were unacceptable.</p> <p>21 But I have also alluded in my report that it was</p> <p>22 unusual because neither FDA nor Teva at the time had</p> <p>23 a specific limit as to what was unacceptable.</p> <p>24 But I don't think I'm debating you,</p> <p>25 Mr. Stanoch. Let me agree that the recall was</p>	<p style="text-align: right;">Page 165</p> <p>1 just to help us with the timeline. Stand by,</p> <p>2 Doctor.</p> <p>3 This will be Teva Exhibit 11. It should</p> <p>4 be Tab 24 in your binder, sir. Let me know when you</p> <p>5 are there.</p> <p>6 (Whereupon, Exhibit 11 was marked for</p> <p>7 identification.)</p> <p>8 THE WITNESS: Should I put away the FDA</p> <p>9 overview exhibit?</p> <p>10 BY MR. STANOCH:</p> <p>11 Q. Yes.</p> <p>12 A. Yes, I see this lift of hold dated July 6,</p> <p>13 2018.</p> <p>14 Q. Very good. So this document appears to be</p> <p>15 a Teva memo dated July 6, 2018, about lifting hold</p> <p>16 status for certain valsartan products, correct?</p> <p>17 A. Yes.</p> <p>18 Q. And so sometime prior to this Teva, as we</p> <p>19 talked about, instituted a hold on all of its</p> <p>20 valsartan products, right?</p> <p>21 A. Yes.</p> <p>22 Q. Right. And then as of July 6, 2018, Teva,</p> <p>23 it appears, lifted its hold on valsartan</p> <p>24 finished-dose products that used non-ZHP valsartan</p> <p>25 API, correct?</p>

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1 A. Yes, I agree.
 2 Q. Uh-huh. And it looks like Teva had been
 3 using valsartan API from Jubilant as well, correct?
 4 A. I would --
 5 MS. LOCKARD: Objection. Speculation.
 6 Foundation.
 7 BY MR. STANOCH:
 8 Q. You can look at the document, Doctor.
 9 A. I see the document. I wasn't aware that
 10 the Teva valsartan products used Jubilant drug
 11 substance.
 12 Q. Oh, I see. You also see that Teva lifted
 13 the hold on valsartan products as of July 6, 2018,
 14 that contained API from Mylan, correct?
 15 A. Yes, I do see that.
 16 Q. Okay. I think you alluded to that a few
 17 questions ago, that you understood that Teva had
 18 used Mylan API for some valsartan products sold in
 19 the U.S., right?
 20 A. Yes, particularly the -- I'm trying to
 21 think. These were the ones made in the Jerusalem
 22 facility.
 23 Q. I would agree with that, sir, yes. I
 24 think we're on the same page.
 25 Are you aware of any testing that Teva did

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1 of its own finished dose that -- just let me start
 2 over.
 3 Are you aware of any testing that Teva did
 4 of its own finished dose that contained API from
 5 Mylan prior to its lifting the hold?
 6 MS. LOCKARD: Objection. Vague.
 7 THE WITNESS: I am not.
 8 BY MR. STANOCH:
 9 Q. Are you aware of whether Mylan tested
 10 valsartan API that it was selling to Teva prior to
 11 Teva's lifting its hold?
 12 A. You know, I have a feeling that there may
 13 be some documentation in the materials considered,
 14 but I'm not aware of it and I didn't cite it in my
 15 report.
 16 Q. Did Teva ever test its own valsartan
 17 finished dose that contained API from Mylan prior to
 18 Teva's recalling that product later in 2018?
 19 MS. LOCKARD: Objection. Vague.
 20 THE WITNESS: I just can't say. I didn't
 21 cite it in my report, so I don't know.
 22 BY MR. STANOCH:
 23 Q. Do you know when, if at all, Mylan tested
 24 valsartan API it was selling to Teva for
 25 nitrosamines after this July 6, 2018, hold memo?

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1 A. Well, my understanding of the sequence of
 2 events is Mylan was saying it couldn't be in their
 3 drug substance for valsartan, but Swissmedic did
 4 some testing, and that's when Teva became aware that
 5 there could be NDEA in the Mylan drug substance.
 6 And that went to Teva's recall in November of 2018.
 7 Q. Uh-huh. Was it appropriate for Teva to
 8 lift its hold on products without testing it?
 9 MS. LOCKARD: Objection. Outside the
 10 scope of his class-certification report.
 11 THE WITNESS: Well, I don't know that they
 12 didn't test it, so I can't respond to that question.
 13 BY MR. STANOCH:
 14 Q. Uh-huh. Are you aware of whether tests
 15 had been developed after June 2018 to detect
 16 nitrosamines?
 17 A. Well, the FDA was working on tests, and I
 18 think Teva was as well. And I think Teva's test
 19 didn't come along -- online until later, but I don't
 20 have those facts readily available now.
 21 Q. Right. Right. Are you aware that, at the
 22 very least, the FDA announced in the summer of 2018
 23 that it had found NDEA in a different manufacturer,
 24 Torrent's valsartan products?
 25 A. I am actually not aware of that.

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1 Q. Uh-huh. And I can certainly pull up the
 2 notice, but the FDA said that Torrent products were
 3 included in the company's recall in August 23rd,
 4 2018. Were you aware of that?
 5 A. I'm sure I looked at it, but I'm not
 6 specifically aware of it until you mention it now,
 7 Mr. Stanoch.
 8 Q. Uh-huh. You would agree, then, that if
 9 the FDA was testing and finding NDEA in a different
 10 manufacturer's product, there were testing methods
 11 available to determine NDEA by August 2018, correct?
 12 MS. LOCKARD: Objection. Speculation.
 13 Vague. And outside the scope of his report.
 14 THE WITNESS: Yeah, I just don't have
 15 information to answer the question.
 16 BY MR. STANOCH:
 17 Q. Uh-huh. Can you say one way or the other
 18 whether Teva ever tested any of its own product for
 19 NDEA prior to its November 2018 recalls?
 20 A. I am sure that information exists, but I
 21 don't have it -- I didn't cite it in my report and I
 22 didn't comment, and so I can't answer.
 23 Q. Okay. That's outside the scope of this
 24 report; is that fair?
 25 A. But I would be guessing just because I

<p style="text-align: right;">Page 170</p> <p>1 don't have the information readily available.</p> <p>2 Q. That's a little different. One is if you</p> <p>3 want the information, you can look at it in your</p> <p>4 report; but if you are not opining on it at this</p> <p>5 time, then you have no opinion at this time, sir.</p> <p>6 So which is it?</p> <p>7 A. I think the way you said it second. I</p> <p>8 have no opinion at this time is a good way to state</p> <p>9 it.</p> <p>10 Q. Very well, sir. We don't need to belabor</p> <p>11 it. Thank you.</p> <p>12 Now, is it appropriate for a drug</p> <p>13 manufacturer to not test its drug for nitrosamines</p> <p>14 after being asked to do so by regulators?</p> <p>15 MS. LOCKARD: Objection. That's a</p> <p>16 liability question, and it's outside the scope of</p> <p>17 his class-certification report. Also incomplete</p> <p>18 hypothetical, vague.</p> <p>19 THE WITNESS: Do I answer?</p> <p>20 MS. LOCKARD: If you are able to.</p> <p>21 THE WITNESS: You know, I would generally</p> <p>22 say the answer to your question is no, it's not</p> <p>23 appropriate.</p> <p>24 BY MR. STANOCH:</p> <p>25 Q. Are you aware of whether Teva ever tested</p>	<p style="text-align: right;">Page 172</p> <p>1 need to have reason to believe you may need to test</p> <p>2 your product for NDEA?</p> <p>3 A. Well, I think in the particular example,</p> <p>4 Mylan was saying they had reason to believe that</p> <p>5 there was no possibility of NDEA being in their drug</p> <p>6 substance.</p> <p>7 Q. Uh-huh.</p> <p>8 A. And Teva could look at the other</p> <p>9 ingredients in the manufacturing process and</p> <p>10 conclude that there was no reason to test --</p> <p>11 Q. Uh-huh.</p> <p>12 A. -- and that it could be in the market.</p> <p>13 And I think that's what this memo speaks to.</p> <p>14 Q. Okay. Did Teva, to your knowledge, in</p> <p>15 fact, look at the Mylan manufacturing process to</p> <p>16 determine whether or not NDEA could arise?</p> <p>17 MS. LOCKARD: Objection. Vague. Outside</p> <p>18 the scope.</p> <p>19 THE WITNESS: I can't say I can speak to</p> <p>20 that, Mr. Stanoch. My belief is they did. They</p> <p>21 were working with Mylan to get the needed</p> <p>22 information. But I don't have specific documents to</p> <p>23 support that view.</p> <p>24 BY MR. STANOCH:</p> <p>25 Q. Uh-huh. If we go back to the exhibit we</p>
<p style="text-align: right;">Page 171</p> <p>1 its valsartan product for any nitrosamines after</p> <p>2 receiving a request from any regulator to do so?</p> <p>3 A. Well, I know they did test their</p> <p>4 nitrosamine -- I'm sorry, their valsartan-containing</p> <p>5 drug products at FDA's request, and they provided</p> <p>6 FDA with that information.</p> <p>7 Q. And that was for NDMA, those tests, I</p> <p>8 think, right?</p> <p>9 A. I agree, it was for NDMA, and I can't say</p> <p>10 whether it was for NDEA.</p> <p>11 Q. Okay. If a finished-dose customer asked</p> <p>12 Teva, do your products contain NDEA, would it be</p> <p>13 appropriate for Teva to conduct that testing and see</p> <p>14 if NDEA is in the products?</p> <p>15 MS. LOCKARD: Objection. Confusing.</p> <p>16 Vague.</p> <p>17 THE WITNESS: Well, I would say if Teva</p> <p>18 had reason to believe that there was no NDEA in</p> <p>19 their valsartan products, Teva would refuse. I</p> <p>20 mean, it might be a very big deal to do that kind of</p> <p>21 testing.</p> <p>22 BY MR. STANOCH:</p> <p>23 Q. Uh-huh.</p> <p>24 A. So I would say it's not appropriate.</p> <p>25 Q. Uh-huh. And what information would you</p>	<p style="text-align: right;">Page 173</p> <p>1 were looking at a moment ago, the lift hold status</p> <p>2 memo; do you have that still, sir?</p> <p>3 A. Yes, I'm looking at it. July 6, 2018?</p> <p>4 Q. Uh-huh. Right. And it states that,</p> <p>5 "Mylan confirmed via e-mail to not have received any</p> <p>6 intermediates from Huahai." Do you see that?</p> <p>7 A. I do see that.</p> <p>8 Q. And further, so that -- strike that.</p> <p>9 So that was one basis for Teva's lifting</p> <p>10 the hold of the Mylan API product, right?</p> <p>11 A. Yes. And you can see in the last bullet</p> <p>12 on the thing where Teva's concluding possibility for</p> <p>13 NDMA impurity is negligible. I don't think the</p> <p>14 focus was on NDEA just yet.</p> <p>15 Q. Uh-huh. Right. At the time Teva lifted</p> <p>16 its hold, it wasn't even discussing, at least in</p> <p>17 this memo, anything about NDEA, right?</p> <p>18 A. Right. And I think that was the case for</p> <p>19 FDA. The concern about NDEA came later, after NDMA.</p> <p>20 Q. Uh-huh. And what is your understanding of</p> <p>21 the route of how nitrosamines came to be in Mylan's</p> <p>22 valsartan API?</p> <p>23 A. I have seen a description of it, and I</p> <p>24 think I have even seen statements from Mylan saying</p> <p>25 that the process was such that nitrosamines couldn't</p>

<p style="text-align: right;">Page 174</p> <p>1 be formed. But beyond that, I don't have any 2 specific information now. 3 Q. I mean, do you understand that it was an 4 issue relating to the residual solvents that Mylan 5 was using in the valsartan API manufacturing 6 process? 7 A. Yes, I do understand that, and that 8 relates to FDA's inspection of Lantech and a warning 9 letter to Lantech about failure to look for the 10 nitrosamine impurity. 11 Q. You are aware that Lantech was the vendor 12 that was managing the solvent recovery process for 13 Mylan when Mylan was making valsartan API for Teva, 14 right? 15 A. Yes, I am aware of that. 16 Q. Uh-huh. And you understand that Lantech 17 was faulted by the FDA for the manner in which it 18 managed the solvent recovery process for Mylan, 19 right? 20 A. Yes, I had that general understanding. 21 Q. And that was the root cause for the NDEA 22 contamination of Mylan's valsartan API, right? 23 A. That's my understanding as well. 24 Q. Did Teva know that Mylan was using a 25 solvent-recovery vendor in the manufacture of</p>	<p style="text-align: right;">Page 176</p> <p>1 not its API supplier was using recycled solvents in 2 the valsartan API manufacturing process? 3 MS. LOCKARD: Objection. Lacks 4 foundation. Outside the scope of his report. 5 THE WITNESS: You know, well, one of the 6 ways I might answer that question is that the DMF 7 system might preclude Teva from knowing because the 8 processes of the DMF may be secret between Mylan and 9 Teva. 10 BY MR. STANOCH: 11 Q. Well, do you see anything suggesting that 12 Teva ever asked Mylan about whether it was using 13 recycled solvents? 14 A. I don't recall seeing any information to 15 that point. 16 Q. Do you recall looking at anything 17 suggesting that Teva ever asked to see Mylan's DMF 18 for valsartan API? 19 MS. LOCKARD: Objection. Asked and 20 answered. It's outside the scope. 21 THE WITNESS: No, it wasn't a focus of my 22 report, and I don't recall seeing it. 23 BY MR. STANOCH: 24 Q. Do you agree that the "Residual Solvents" 25 chapter of the USP would be part of the chapters and</p>
<p style="text-align: right;">Page 175</p> <p>1 valsartan API? 2 A. I don't know that. I couldn't answer that 3 question. 4 Q. All right. Sitting here today, can you 5 recall anything you saw suggesting that Teva ever 6 asked Mylan if Mylan was using a vendor for the 7 solvent recovery process in the manufacture of 8 valsartan API? 9 A. I can't answer that. I don't have that 10 information. 11 Q. Uh-huh. Did Teva know that Mylan was 12 using recycled solvents at all in the manufacture of 13 valsartan API? 14 A. I can't say what Teva knew or didn't know. 15 Q. Sitting here today, can you tell me 16 anything you saw suggesting, even, that Teva knew 17 that Mylan was using recycled solvents in the 18 manufacture of valsartan API? 19 A. I think there is information about it, but 20 I don't have it and I can't comment. 21 Q. Uh-huh. Right. You can't elaborate any 22 more on that, can you? 23 A. No. 24 Q. Right. Shouldn't Teva, as the 25 finished-dose manufacturer, understand whether or</p>	<p style="text-align: right;">Page 177</p> <p>1 notices which manufacturers should take into account 2 when they are manufacturing their own finished-dose 3 valsartan? 4 MS. LOCKARD: Objection. Vague. 5 THE WITNESS: I think "Residual Solvents" 6 is an ICH document that is important to 7 manufacturers as a recommendation, so I think I 8 would answer that yes. 9 BY MR. STANOCH: 10 Q. Uh-huh. Do you know whether Teva adhered 11 to the USP "Residual Solvents" Chapter 467 in 12 assessing the valsartan API it purchased from Mylan? 13 A. I think my understanding would be that in 14 the certificate of analysis for valsartan, there may 15 be a test for residual solvents. And we could 16 certainly look at that. 17 Q. Well, you looked at a number of 18 certificates, I believe, listed in your materials 19 considered, right? 20 A. No. That doesn't mean I looked at them. 21 They are listed in my materials considered, but they 22 weren't important to my report and I didn't cite 23 them. 24 Q. Fair enough. Can you say sitting here 25 today whether you saw any mention of the use of</p>

<p style="text-align: right;">Page 178</p> <p>1 recycled solvents by Mylan in the manufacture of 2 valsartan API? 3 A. No, I didn't see anything about recycled 4 solvents. 5 Q. And a moment ago you were talking about 6 the potential confidentiality of DMFs. Do you 7 remember that? 8 A. I do. 9 Q. Is the mere existence of a third-party 10 vendor secret? 11 MS. LOCKARD: Objection. Foundation. 12 Speculation. 13 THE WITNESS: I don't quite understand. 14 Secret from whom? 15 BY MR. STANOCH: 16 Q. Does the fact that Mylan was using a 17 third-party vendor, Lantech, to manage the solvent 18 recovery process for valsartan API -- strike that. 19 You were suggesting, were you not, that 20 some of Mylan's DMF might have been confidential and 21 not shareable with Teva, right? 22 A. Right, right. 23 Q. Right. So is it your position, sir, that 24 the mere fact that Mylan was using a third-party 25 vendor at all for the solvent recovery process was</p>	<p style="text-align: right;">Page 180</p> <p>1 These are sellers of a drug substance that Teva 2 purchased. 3 BY MR. STANOCH: 4 Q. Uh-huh. So it's your position that -- oh, 5 strike that. 6 Would it surprise you to know that Mylan 7 was contracting with a third-party vendor in India 8 who had never been inspected by the FDA? 9 A. No, it wouldn't surprise me. 10 Q. And do you think Teva would have any issue 11 if it learned that Mylan was contracting with a 12 third-party vendor in India who had never been 13 inspected by the FDA? 14 MS. LOCKARD: Objection -- 15 MR. STOY: Frank Stoy for Mylan. I am 16 just going to object to the form of the question. 17 (Reporter clarification.) 18 MR. STOY: Yes, I just stated an objection 19 to the form of the question. Thank you. 20 MS. LOCKARD: I objected as well as vague. 21 And calls for speculation. 22 THE WITNESS: But I feel like I'm losing 23 Mr. Stanoch. 24 BY MR. STANOCH: 25 Q. Can you hear me, sir?</p>
<p style="text-align: right;">Page 179</p> <p>1 something that would be confidential and not 2 shareable with Teva? 3 A. Well, it could be. I just don't know what 4 Mylan wanted to keep confidential in the DMF. 5 Q. Uh-huh. And if -- oh. 6 A. And again, remember, typically what you 7 see in the DMF for the purchaser, in this case, 8 Teva, is the certificate of analysis, the 9 specification for the drug substance. 10 Q. And again, those certificates and 11 analysis, to the extent you recall sitting here 12 today, made no mention of the use of recycled 13 solvents? 14 A. It may have a specification for residual 15 solvents. We would have to look at one to see. But 16 I don't think that necessarily would tell anything 17 about whether the solvents were recycled or not. 18 Q. Uh-huh. And one way Teva could have had 19 additional information about Lantech would be if it 20 had a quality agreement in place with Mylan, 21 correct? 22 MS. LOCKARD: Objection. Speculation. 23 THE WITNESS: You know, quality agreements 24 may relate to contract manufacturers, but for both 25 ZHP and Mylan, these are not contract manufacturers.</p>	<p style="text-align: right;">Page 181</p> <p>1 A. Yeah, now I can hear you clearly. 2 Q. I will repeat the -- 3 A. Can you repeat -- 4 Q. I would love to because of the 5 interference -- I don't mean that pejoratively -- 6 from defense counsel. 7 Sir, do you think Teva would have an issue 8 if it learned that Mylan was using a third-party 9 vendor in India who had never been inspected by the 10 FDA to manage the solvent recovery process? 11 MS. LOCKARD: Same objection. 12 THE WITNESS: I can't really speculate 13 what Teva would think about it. It doesn't seem to 14 me a big issue whether there is or is not an FDA 15 inspection. 16 BY MR. STANOCH: 17 Q. It's not a big issue if Teva was buying 18 valsartan API from Mylan where Mylan was using a 19 third-party vendor not disclosed to Teva who had 20 never been inspected by the FDA; is that your 21 testimony? 22 A. I'm not really an expert on solvent 23 recovery processes, but my understanding is that 24 many companies use them. It's not unusual. And to 25 me it might be part of the DMF that Mylan would want</p>

<p style="text-align: right;">Page 182</p> <p>1 to keep confidential.</p> <p>2 And then the issue of an FDA inspection</p> <p>3 is -- to tell you the truth, Mr. Stanoch, when I saw</p> <p>4 that FDA had inspected Lantech, this was the first</p> <p>5 time I had ever heard of FDA inspecting a</p> <p>6 solvent-recovery manufacturer.</p> <p>7 Q. Uh-huh. And that happened after news of</p> <p>8 the nitrosamines broke in 2018, though, right?</p> <p>9 A. Yes, that's when the inspection occurred</p> <p>10 for Lantech.</p> <p>11 Q. Right. And Teva never inspected Lantech</p> <p>12 prior to 2018, did it?</p> <p>13 A. I don't know that.</p> <p>14 Q. Right. And did you see anything in any of</p> <p>15 the documents you reviewed suggesting that Teva ever</p> <p>16 inspected Lantech prior to 2018?</p> <p>17 A. No, I didn't see anything like that.</p> <p>18 Q. And you never saw anything even suggesting</p> <p>19 Teva knew who Lantech was prior to 2018, correct?</p> <p>20 A. I never saw anything to that point.</p> <p>21 Q. Would it surprise you to know that Mylan</p> <p>22 was also using Lantech to do second-crop harvesting</p> <p>23 of valsartan API?</p> <p>24 MS. LOCKARD: Objection. Foundation.</p> <p>25 Speculation. Outside the scope of his report.</p>	<p style="text-align: right;">Page 184</p> <p>1 support an answer.</p> <p>2 BY MR. STANOCH:</p> <p>3 Q. Okay. Wouldn't a contract between Mylan</p> <p>4 and Teva allow those two firms to exchange</p> <p>5 confidential information?</p> <p>6 MS. LOCKARD: Objection. Speculation.</p> <p>7 Outside the scope.</p> <p>8 THE WITNESS: I could imagine a contract</p> <p>9 that would support that kind of exchange of</p> <p>10 information.</p> <p>11 BY MR. STANOCH:</p> <p>12 Q. Right.</p> <p>13 A. But it can occur without a contract.</p> <p>14 Q. It certainly could, but that exchange did</p> <p>15 not occur here between Teva and Mylan about the</p> <p>16 recycled solvents and Lantech, did it?</p> <p>17 A. I just have no information to that point,</p> <p>18 but if that's what you say, I certainly wouldn't</p> <p>19 debate you.</p> <p>20 Q. And you would agree, though, that Teva</p> <p>21 could have contractually required Mylan to disclose</p> <p>22 information about the solvent recovery process,</p> <p>23 correct?</p> <p>24 MS. LOCKARD: Objection. Speculation.</p> <p>25 Outside the scope.</p>
<p style="text-align: right;">Page 183</p> <p>1 THE WITNESS: I don't understand the</p> <p>2 question and I have no information to answer it.</p> <p>3 BY MR. STANOCH:</p> <p>4 Q. Uh-huh. Teva could not make its</p> <p>5 assessment about the recycled-solvent process</p> <p>6 without knowing anything about it, correct?</p> <p>7 MS. LOCKARD: Objection. Vague.</p> <p>8 THE WITNESS: That seems like a generally</p> <p>9 true statement, so I can agree.</p> <p>10 BY MR. STANOCH:</p> <p>11 Q. Uh-huh. And absent a contractual</p> <p>12 arrangement that would obligate Mylan to disclose</p> <p>13 that information, Mylan didn't have to disclose it</p> <p>14 to Teva; is that your statement?</p> <p>15 A. No, I'm not making that statement.</p> <p>16 Q. Uh-huh. If there was a contract between</p> <p>17 Mylan and Teva that governed disclosure of the</p> <p>18 processes and entities involved in the valsartan API</p> <p>19 manufacturing process, Teva could have learned about</p> <p>20 Lantech prior to all the recalls in 2018, right?</p> <p>21 MS. LOCKARD: Objection. Speculation.</p> <p>22 Foundation. Outside the scope of his</p> <p>23 class-certification opinions.</p> <p>24 THE WITNESS: Yeah, I would have to</p> <p>25 speculate on that. I just have no information to</p>	<p style="text-align: right;">Page 185</p> <p>1 THE WITNESS: Yeah, again, everything you</p> <p>2 are asking me, I would be required to speculate</p> <p>3 because I just don't have the information.</p> <p>4 BY MR. STANOCH:</p> <p>5 Q. Do you know whether Teva ever performed a</p> <p>6 residual solvent analysis with respect to Mylan</p> <p>7 valsartan API?</p> <p>8 A. I do not.</p> <p>9 Q. Do you know whether Mylan itself ever</p> <p>10 conducted a residual solvent analysis for the</p> <p>11 valsartan API it made?</p> <p>12 A. I do not know that.</p> <p>13 Q. Uh-huh. Did Teva ever ask to audit</p> <p>14 Lantech?</p> <p>15 A. Not that I'm aware of.</p> <p>16 Q. Right. Teva didn't even know who Lantech</p> <p>17 was, right?</p> <p>18 A. I don't know that.</p> <p>19 Q. Do you have any information suggesting</p> <p>20 that Teva knew about Lantech and its role in the</p> <p>21 Mylan valsartan API manufacturing process prior to</p> <p>22 the recalls?</p> <p>23 MS. LOCKARD: Objection. Speculation.</p> <p>24 Foundation. Outside the scope.</p> <p>25 THE WITNESS: I just don't know, and it</p>

<p style="text-align: right;">Page 186</p> <p>1 wasn't pertinent to my report.</p> <p>2 BY MR. STANOCH:</p> <p>3 Q. Uh-huh. Are you aware of any evidence</p> <p>4 that Teva ever reviewed ZHP's route of synthesis for</p> <p>5 valsartan API prior to the 2018 recalls?</p> <p>6 MS. LOCKARD: Outside the scope.</p> <p>7 Objection.</p> <p>8 THE WITNESS: Well, I think if we look at</p> <p>9 the Watson CBE-30s -- Watson, of course, is a</p> <p>10 predecessor company to Teva -- there was information</p> <p>11 about the route of synthesis and the synthesis</p> <p>12 change.</p> <p>13 BY MR. STANOCH:</p> <p>14 Q. You are talking about the ZHP process</p> <p>15 change, correct?</p> <p>16 A. Yes.</p> <p>17 Q. Right. And regarding that, ZHP was</p> <p>18 changing its manufacturing process for valsartan API</p> <p>19 that it was selling to, at the time, Actavis,</p> <p>20 correct?</p> <p>21 A. I would say Watson, but they were all</p> <p>22 predecessor companies to Teva.</p> <p>23 Q. That's fine. We can agree that Watson was</p> <p>24 a predecessor to Actavis and then Actavis was a</p> <p>25 predecessor to current Teva, right?</p>	<p style="text-align: right;">Page 188</p> <p>1 Q. So the fact that Watson characterized the</p> <p>2 ZHP process change as minor to moderate meant that</p> <p>3 it could implement its change immediately if it</p> <p>4 wanted, correct?</p> <p>5 A. Well, I would say the letter was the</p> <p>6 CBE-30, so they would wait to hear from FDA and then</p> <p>7 they could implement after 30 days.</p> <p>8 Q. Uh-huh. And in that context of that</p> <p>9 submission, did Watson, to your knowledge, review</p> <p>10 ZHP's entire DMF?</p> <p>11 A. As far as I know, they did not.</p> <p>12 Q. All right. Did Watson, Actavis, or Teva,</p> <p>13 to your knowledge, ever ask ZHP for a copy of ZHP's</p> <p>14 DMF for valsartan API?</p> <p>15 A. As far as I know, they did not.</p> <p>16 Q. Nothing stopped any of them from</p> <p>17 requesting that, correct?</p> <p>18 A. Well, I think it would be counter to the</p> <p>19 way a DMF works, that it's a separate filing to the</p> <p>20 agency. So I would say Teva would not ask for it.</p> <p>21 Q. Well, that wasn't quite my question, sir.</p> <p>22 The question was that nothing stopped Teva or its</p> <p>23 predecessor entities from asking ZHP for a copy of</p> <p>24 the DMF for valsartan API, correct?</p> <p>25 A. I think you are correct. I mean, the two</p>
<p style="text-align: right;">Page 187</p> <p>1 A. Yes, that sounds right.</p> <p>2 Q. Great. So we can use -- we can understand</p> <p>3 that as we go through. So ZHP changed it</p> <p>4 manufacturing process for the valsartan API it was</p> <p>5 selling to Watson, right?</p> <p>6 A. Yes, that's correct.</p> <p>7 Q. And ZHP characterized that as a minor to</p> <p>8 moderate change, correct?</p> <p>9 A. I would have to see the letters from</p> <p>10 Watson to FDA, but I think you are correct.</p> <p>11 Q. And a minor to moderate process change</p> <p>12 does not require preapproval from the FDA, does it?</p> <p>13 A. Well, I couldn't agree with that, because</p> <p>14 Watson was asking for FDA approval, but they</p> <p>15 submitted it as a CBE-30.</p> <p>16 Q. Right. And a CBE-30, Change Being</p> <p>17 Effected, does not technically require preapproval</p> <p>18 by the FDA, correct?</p> <p>19 A. The way I would say it is FDA will always</p> <p>20 come in and review it, but the change can be</p> <p>21 implemented if FDA doesn't respond within 30 days.</p> <p>22 Q. Right. A major process change requires a</p> <p>23 different level of review by the FDA, correct?</p> <p>24 A. That would be called the postapproval</p> <p>25 supplement.</p>	<p style="text-align: right;">Page 189</p> <p>1 companies could agree to completely share the</p> <p>2 contents of the DMF.</p> <p>3 Q. Right.</p> <p>4 A. But typically a DMF is not shared with the</p> <p>5 purchaser, such as Teva.</p> <p>6 Q. Uh-huh. And the DMF was not shared in</p> <p>7 this instance, as far as you know, with Teva or its</p> <p>8 predecessor entities?</p> <p>9 MS. LOCKARD: Objection. Asked and</p> <p>10 answered.</p> <p>11 THE WITNESS: I have to say I just don't</p> <p>12 know. If I had to guess, I would say not.</p> <p>13 BY MR. STANOCH:</p> <p>14 Q. Uh-huh. To your knowledge, did Teva ever</p> <p>15 ask ZHP to confirm that ZHP's valsartan API did not</p> <p>16 contain any genotoxic substances?</p> <p>17 A. As far as I know, it was not an issue or a</p> <p>18 basis for communication until the summer of 2018.</p> <p>19 Q. Nothing's prevented Teva from ever asking</p> <p>20 ZHP to confirm that ZHP's valsartan API did not</p> <p>21 contain any genotoxic substances, correct?</p> <p>22 A. Are you saying nothing prevented them?</p> <p>23 Q. Yes. I'll restate it. Nothing prevented</p> <p>24 Teva from ever asking ZHP to confirm that ZHP's</p> <p>25 valsartan API did not contain any genotoxic</p>

<p style="text-align: right;">Page 190</p> <p>1 substances, correct?</p> <p>2 A. Well, if it was expected, I suppose Teva</p> <p>3 could certainly have asked, but it was unexpected.</p> <p>4 Q. Well, it was unexpected because ZHP said</p> <p>5 so; isn't that right?</p> <p>6 MS. LOCKARD: Objection to form.</p> <p>7 THE WITNESS: No, the reason I say it was</p> <p>8 unexpected, because FDA said so.</p> <p>9 BY MR. STANOCH:</p> <p>10 Q. Well, FDA said it's unexpected because</p> <p>11 that's how ZHP characterized it originally when it</p> <p>12 was forced to break all this news in June 2018;</p> <p>13 isn't that right?</p> <p>14 MS. LOCKARD: Objection to form.</p> <p>15 MS. HILL: Objection. Argument.</p> <p>16 THE WITNESS: I just don't know that,</p> <p>17 Mr. Stanoch. If you know that, it's news to me.</p> <p>18 BY MR. STANOCH:</p> <p>19 Q. Uh-huh. Uh-huh. Do you have any</p> <p>20 information as to where FDA may have gotten the term</p> <p>21 "unexpected" as to the nitrosamines found in</p> <p>22 valsartan products?</p> <p>23 A. I don't.</p> <p>24 Q. And would it surprise you if it came</p> <p>25 originally from ZHP?</p>	<p style="text-align: right;">Page 192</p> <p>1 API from ZHP?</p> <p>2 A. I think now they have resolved their</p> <p>3 issues with FDA, as I understand it, that arose and</p> <p>4 were summarized in the warning letter, and</p> <p>5 everything is fine between FDA and the company.</p> <p>6 Q. Uh-huh. So you would?</p> <p>7 A. Yes.</p> <p>8 Q. Uh-huh. How about before 2018?</p> <p>9 MS. LOCKARD: Objection. Vague.</p> <p>10 THE WITNESS: Well, I would say yes. My</p> <p>11 understanding is they had good FDA inspections, and</p> <p>12 many companies get warning letters where things can</p> <p>13 be resolved, and that's what happened for ZHP.</p> <p>14 BY MR. STANOCH:</p> <p>15 Q. Uh-huh. And it's important, then, to know</p> <p>16 if your API supplier is receiving any adverse</p> <p>17 inspections from the FDA, correct?</p> <p>18 A. That's a separate topic. And -- is that a</p> <p>19 question? I'm sorry.</p> <p>20 Q. It's important to know if your API</p> <p>21 supplier is receiving any adverse inspection</p> <p>22 findings from the FDA, correct?</p> <p>23 A. I think it could be important, yes.</p> <p>24 Q. Okay. Yes. And a reasonable</p> <p>25 pharmaceutical manufacturer would want to know if</p>
<p style="text-align: right;">Page 191</p> <p>1 MS. LOCKARD: Objection. Speculation.</p> <p>2 Foundation.</p> <p>3 THE WITNESS: Yeah, I just can't answer.</p> <p>4 I don't know where it came from.</p> <p>5 BY MR. STANOCH:</p> <p>6 Q. Uh-huh. If ZHP told the world this</p> <p>7 nitrosamine impurity was unexpected, but it had</p> <p>8 information suggesting it knew a year earlier, would</p> <p>9 that be important?</p> <p>10 MS. LOCKARD: Objection to form.</p> <p>11 THE WITNESS: I just have to speculate. I</p> <p>12 don't know when ZHP had its information. It seemed</p> <p>13 to me it was closer to the summer of 2018 time</p> <p>14 frame.</p> <p>15 BY MR. STANOCH:</p> <p>16 Q. Uh-huh. Did you evaluate whether ZHP had</p> <p>17 any information suggesting there may be nitrosamines</p> <p>18 in its valsartan API prior to June 2018?</p> <p>19 A. I did not see any information to that</p> <p>20 point.</p> <p>21 Q. Was that even part of your analysis for</p> <p>22 purposes of your class-certification report?</p> <p>23 A. No.</p> <p>24 Q. Uh-huh. In the context of your consulting</p> <p>25 work, sir, would you advise a company to purchase</p>	<p style="text-align: right;">Page 193</p> <p>1 its API supplier is receiving adverse inspections</p> <p>2 and findings from the FDA, correct?</p> <p>3 MS. LOCKARD: Objection. Outside the</p> <p>4 scope. That's clearly a liability question.</p> <p>5 THE WITNESS: And I -- you know, there are</p> <p>6 so many variables underlying your question. I mean,</p> <p>7 FDA may inspect and make a few observations that are</p> <p>8 quickly resolved. I'm not sure that needs to be</p> <p>9 communicated to buyers.</p> <p>10 BY MR. STANOCH:</p> <p>11 Q. Uh-huh. If a manufacturer of</p> <p>12 finished-dose product learns about an FDA inspection</p> <p>13 and requests information about it from its API</p> <p>14 supplier, would it be your expectation that the API</p> <p>15 supplier would provide the information?</p> <p>16 MS. LOCKARD: Objection. Speculation.</p> <p>17 Foundation. Incomplete hypothetical.</p> <p>18 THE WITNESS: Yes, and I just don't have</p> <p>19 any basis to have an answer to that question.</p> <p>20 BY MR. STANOCH:</p> <p>21 Q. Well, you consult pharmaceutical</p> <p>22 manufacturers, don't you, sir?</p> <p>23 A. I would say now I am doing primarily</p> <p>24 litigation, and I have never consulted on the type</p> <p>25 of questions you are raising now.</p>

<p style="text-align: right;">Page 194</p> <p>1 Q. Right, uh-huh. Have you ever advised a 2 company that it's prudent for them to have all 3 available information about regulatory inspections 4 of their API supplier? 5 A. I have not. 6 Q. Uh-huh. Are there ways for pharmaceutical 7 manufacturers to independently check on whether 8 their API suppliers have had adverse regulatory 9 findings? 10 A. Well, certainly a warning letter is 11 public, so that could come to light independent of a 12 drug-substance manufacturer. 13 Q. Uh-huh. Are you aware of any processes 14 Teva had in place prior to June 2018 to monitor 15 whether its API suppliers were receiving adverse 16 findings from regulators? 17 A. I am not. 18 Q. Uh-huh. And back to ZHP and Teva. To 19 your knowledge, Teva never asked ZHP to confirm that 20 ZHP's valsartan API did not contain any genotoxic 21 substances, correct? 22 MS. LOCKARD: Objection. Asked and 23 answered. 24 THE WITNESS: Yes, I am not aware of any 25 communication like that.</p>	<p style="text-align: right;">Page 196</p> <p>1 MR. STANOCH: Counsel, I'm not debating 2 you now on the record. I'm going to keep asking my 3 questions. You are lodging your objections. I'm 4 asking questions on the facts on which he is opining 5 about. It's within the scope of his report. 6 He says a number of factual -- 7 MS. LOCKARD: I just want to -- 8 MR. STANOCH: Excuse me. He makes a 9 number of statements about facts. I'm entitled to 10 probe the facts as they relate to the opinions in 11 this report. 12 MS. LOCKARD: You are not asking about 13 facts, though. You are asking about his opinion as 14 to whether something is reasonable, prudent, 15 appropriate, and those are the questions that I'm 16 objecting to. Now, I understand -- 17 MR. STANOCH: You have stated your 18 objections. 19 MS. LOCKARD: -- you are going to keep 20 asking, but we're going to move to strike all this 21 testimony and you are not going to be able to come 22 back and ask him or anyone else these questions. 23 MR. STANOCH: Well, I disagree with that. 24 I'm asking him questions relating to the facts and 25 the opinions in this report. And we will keep</p>
<p style="text-align: right;">Page 195</p> <p>1 BY MR. STANOCH: 2 Q. Uh-huh. Wouldn't it have been prudent for 3 Teva to request such a statement from ZHP regarding 4 the valsartan API? 5 MS. LOCKARD: Objection. Outside the 6 scope of his report. It's liability opinion. 7 You are just -- I'm sorry, Mr. Stanoch, 8 but you have just completely disregarded any sort of 9 line, bright or not, between liability opinion and 10 his class-certification opinion. I'm honestly at a 11 loss as to whether we need to suspend and call a 12 judge or meet and confer on this. 13 But, I mean, I hate to just keep objecting 14 to every question, but every question is, you know, 15 what would a prudent manufacturer do? What would be 16 reasonable? You know, what should they do? Would 17 it be appropriate? These are all liability 18 opinions. 19 MR. STANOCH: Are you done, Counsel? 20 MS. LOCKARD: No, because I'm having a 21 problem here. 22 MR. STANOCH: Are you done, Counsel? 23 MS. LOCKARD: No. Do you want to go off 24 the record or you want to discuss it on the record? 25 What is your response?</p>	<p style="text-align: right;">Page 197</p> <p>1 going. 2 MS. LOCKARD: Well, this will be taken up 3 with Judge Vanaskie, so -- 4 MR. STANOCH: I don't appreciate the 5 threat, Counsel. 6 MS. LOCKARD: It is not a threat -- a 7 statement. But go ahead. 8 MR. STANOCH: For the record, Counsel, 9 I'll state that in his own report, Dr. Williams 10 opines on reasonableness a number of times in terms 11 of methods, in terms of what one would do, in terms 12 of risk assessments, et cetera, so it's in the 13 report. We can look at it later. 14 Q. So, Doctor -- 15 MS. LOCKARD: I disagree with your 16 assessment. 17 (Reporter clarification.) 18 MS. LOCKARD: I said I disagree with the 19 assessment, but go ahead. 20 BY MR. STANOCH: 21 Q. Uh-huh. Dr. Williams, you state in 22 Paragraph 84 of your report that there is no issue 23 with the FDA inspection of ZHP in 2017 because an 24 EIR was provided; is that right? 25 A. Wait a minute, if I could get to where you</p>

<p>Page 198</p> <p>1 are now. Which paragraph?</p> <p>2 Q. 84.</p> <p>3 A. And what page? Yeah.</p> <p>4 Q. I don't have a printed copy of the report</p> <p>5 you produced this morning, so I can't tell you the</p> <p>6 exact page, sir. Sorry. It's Paragraph 84.</p> <p>7 A. Page 28. Yes. And, of course, others</p> <p>8 will comment on ZHP's inspectional history, but this</p> <p>9 is an example of an inspection that ZHP got in 2017,</p> <p>10 an FDA 483 with a small number of observations, and</p> <p>11 as FDA does, they provided an EIR, indicating that</p> <p>12 the inspection was closed.</p> <p>13 Q. Are you suggesting here that because the</p> <p>14 FDA did not continue the inspection, there were no</p> <p>15 problems with ZHP's valsartan API?</p> <p>16 A. Well, that's a difficult question to give</p> <p>17 a conjecture about. What I would say is I can't say</p> <p>18 more than what the facts state, that ZHP responded</p> <p>19 to the observations, FDA found them satisfactory and</p> <p>20 issued an EIR.</p> <p>21 Q. Was Teva ever made aware of the FDA</p> <p>22 inspection of ZHP's facility in 2017? Did it learn</p> <p>23 of that in the year 2017?</p> <p>24 A. I don't know that.</p> <p>25 Q. Right. Do you know when, if at all, Teva</p>	<p>Page 200</p> <p>1 was reviewing the DMF and was certainly likely to</p> <p>2 imagine that FDA would inspect ZHP, so it would be</p> <p>3 hard to imagine that Teva didn't have some</p> <p>4 understanding of those possibilities. But in terms</p> <p>5 of the discrete facts of those possibilities, I have</p> <p>6 no information.</p> <p>7 Q. Uh-huh. Is there only a potential cGMP</p> <p>8 problem with an API supplier if the FDA catches it</p> <p>9 first?</p> <p>10 A. No. I don't think that is a fair</p> <p>11 statement. I would say the essence of GMPs is the</p> <p>12 manufacturer is supposed to create their own</p> <p>13 approach to GMPs that then is suitable for an FDA</p> <p>14 inspection, but the FDA inspection may occur</p> <p>15 infrequently.</p> <p>16 Q. Uh-huh. Right. It's incumbent on a</p> <p>17 manufacturer sourcing API to conduct its own due</p> <p>18 diligence of the API manufacturer, correct?</p> <p>19 A. Are you talking about the purchaser?</p> <p>20 Q. Yes. It's incumbent on the finished-dose</p> <p>21 manufacturer purchasing API to conduct its own due</p> <p>22 diligence of the API supplier, correct?</p> <p>23 A. I think that's a reasonable statement,</p> <p>24 yes.</p> <p>25 Q. Uh-huh. And further down in your report,</p>
<p>Page 199</p> <p>1 learned that FDA inspected ZHP's API facility in</p> <p>2 2017?</p> <p>3 A. I'm not aware of what FDA knew about ZHP</p> <p>4 inspectional history. Of course they knew about the</p> <p>5 warning letter because that was public.</p> <p>6 Q. Well, the warning letter was from 2018,</p> <p>7 after the recalls, right?</p> <p>8 A. Yes.</p> <p>9 Q. Right. So I'm asking -- a different</p> <p>10 question is: What is your understanding of when</p> <p>11 Teva knew about the FDA inspection of ZHP that</p> <p>12 occurred in 2017?</p> <p>13 A. I have no information about that.</p> <p>14 Q. Right. So you don't know one way or the</p> <p>15 other when Teva might have learned that the FDA</p> <p>16 inspected ZHP's API facility in 2017?</p> <p>17 A. Yes, I don't know that.</p> <p>18 Q. Do you know when if at all ZHP revealed</p> <p>19 the observations from the 2017 FDA inspection to</p> <p>20 Teva?</p> <p>21 A. I don't know that they revealed it to</p> <p>22 Teva.</p> <p>23 Q. Was Teva ever relying on the FDA to</p> <p>24 determine the acceptability of ZHP's valsartan API?</p> <p>25 A. Well, I think Teva would be aware that FDA</p>	<p>Page 201</p> <p>1 beginning Section F, do you see this? It's "FDA</p> <p>2 Inspections of Teva Drug Product Manufacturing</p> <p>3 Facilities"; do you see that, sir?</p> <p>4 A. I do.</p> <p>5 Q. Okay. And here you talk about FDA</p> <p>6 inspections of Teva's own finished-dose facilities</p> <p>7 that had been manufacturing valsartan prior to the</p> <p>8 recalls; is that fair?</p> <p>9 A. Yes, FDA inspections.</p> <p>10 Q. Right. And are you suggesting that just</p> <p>11 because the FDA didn't find a problem relating to</p> <p>12 valsartan, that there was no issue with the</p> <p>13 valsartan API that the Malta and Jerusalem</p> <p>14 facilities were sourcing from ZHP and Mylan?</p> <p>15 A. I don't know that. I couldn't comment.</p> <p>16 Q. And are you suggesting here that because</p> <p>17 the FDA did not find any adulteration during the</p> <p>18 inspections you list in your report here, that</p> <p>19 Teva's product could not be adulterated with</p> <p>20 nitrosamines during these same time periods?</p> <p>21 A. I'm saying that Teva in my report had</p> <p>22 recalled all its valsartan products from the market</p> <p>23 before FDA made any determinations related to</p> <p>24 adulteration.</p> <p>25 Q. Well, Teva's products had API with</p>

<p style="text-align: right;">Page 202</p> <p>1 nitrosamines in it prior to the recalls, right?</p> <p>2 A. Yes, I think that was the basis for the</p> <p>3 recall.</p> <p>4 Q. Right. So are you telling me that a</p> <p>5 valsartan product made by Teva the day before the</p> <p>6 recalls with nitrosamines is not adulterated, but</p> <p>7 then once the recall is issued the next day, now</p> <p>8 that product is adulterated?</p> <p>9 A. No, I'm saying the adulteration label, if</p> <p>10 somebody wanted to say, when did it occur, it</p> <p>11 occurred with the warning letters that went to ZHP</p> <p>12 and Mylan, and it also occurred after FDA set limits</p> <p>13 for the nitrosamine impurities in December 2018.</p> <p>14 But before that, Teva had recalled all product from</p> <p>15 the U.S. market.</p> <p>16 Q. Uh-huh.</p> <p>17 A. Both made in Jerusalem and Malta.</p> <p>18 Q. Uh-huh. Are you saying that valsartan</p> <p>19 sold by Teva prior to the FDA's issuance of warning</p> <p>20 letters to ZHP and Mylan could not be considered</p> <p>21 adulterated?</p> <p>22 A. Yes.</p> <p>23 Q. So a Teva valsartan product on a certain</p> <p>24 day that had nitrosamines in it is not adulterated</p> <p>25 until the FDA issues a warning letter to ZHP or</p>	<p style="text-align: right;">Page 204</p> <p>1 A. Yes, yes, go ahead.</p> <p>2 Q. Number two would be when FDA issued a</p> <p>3 warning letter to Mylan, right? Right?</p> <p>4 A. Yes, uh-huh.</p> <p>5 Q. Number three would be when FDA set interim</p> <p>6 limits, which you say occurred in December of 2018,</p> <p>7 correct?</p> <p>8 A. Yes, I think that's -- I'm looking at my</p> <p>9 report to see if those opinions are clearly stated.</p> <p>10 Let me check. But that corresponds to my opinion.</p> <p>11 Q. So let's say the FDA never set interim</p> <p>12 limits and let's say the FDA never issued warning</p> <p>13 letters to ZHP or Mylan. In that case, Teva's</p> <p>14 finished-dose valsartan could never be considered</p> <p>15 adulterated, according to you?</p> <p>16 A. Yes, I think the issue of adulteration</p> <p>17 arose and was determined, to the extent it was</p> <p>18 determined at all, after Teva had recalled all</p> <p>19 product from the market.</p> <p>20 Q. So then the answer is that Teva's</p> <p>21 valsartan products would never be considered</p> <p>22 adulterated in a world where the FDA did not issue</p> <p>23 warning letters to ZHP and Mylan and the FDA set no</p> <p>24 interim limits?</p> <p>25 A. Yeah, I don't think FDA -- yeah, if we</p>
<p style="text-align: right;">Page 203</p> <p>1 Mylan, and then once that happens, then it's</p> <p>2 adulterated?</p> <p>3 A. That's when a formal regulatory definition</p> <p>4 of adulteration could be stated to have occurred.</p> <p>5 And it could also have been stated to have occurred</p> <p>6 when FDA set limits for nitrosamine in December of</p> <p>7 2018.</p> <p>8 Q. So going back to our examples we had</p> <p>9 talked about before a couple breaks, if there is a</p> <p>10 product that is containing anthrax, it's not</p> <p>11 adulterated until the FDA issues a Form 483?</p> <p>12 A. No, no, no. I would say a 483 is not a</p> <p>13 FDA determination of adulteration. A regulatory</p> <p>14 determination of adulteration by FDA is a very</p> <p>15 serious matter and, you know, it's carefully</p> <p>16 considered by FDA, and I am suggesting that it could</p> <p>17 have been determined to have occurred on those three</p> <p>18 points that I just stated.</p> <p>19 But Teva had recalled all of its product</p> <p>20 before FDA made any kind of statement that could be</p> <p>21 deemed an interpretation of adulteration.</p> <p>22 Q. So it sounds like the only three points</p> <p>23 that you say adulteration could be found is when,</p> <p>24 number one, FDA issued a warning letter to ZHP,</p> <p>25 right?</p>	<p style="text-align: right;">Page 205</p> <p>1 say, was the Mylan product adulterated, I would say</p> <p>2 it couldn't -- FDA had not made a decision in that</p> <p>3 regard at least until those three prongs, if you</p> <p>4 will, had been met.</p> <p>5 Q. Say a warning letter finds a product</p> <p>6 adulterated on January 1, 2022. Does that mean that</p> <p>7 on December 31, 2021, that same product was not</p> <p>8 adulterated?</p> <p>9 A. Yeah, I think the issue of adulteration</p> <p>10 is -- and I'm looking at page 8 in my opinion, under</p> <p>11 B, and my opinion is clear. "My opinion that Teva's</p> <p>12 valsartan products were, at all times prior to</p> <p>13 Teva's voluntary recalls, AB-rated to their branded</p> <p>14 counterparts and were not adulterated or</p> <p>15 misbranded." That's what I'm saying.</p> <p>16 Now, if somebody wants to raise an issue</p> <p>17 of when adulteration occurred, I would say it was</p> <p>18 when the warning letters went to ZHP and Mylan or</p> <p>19 when FDA set limits on the nitrosamine impurities in</p> <p>20 December 2018. I think that's a very clear</p> <p>21 conclusion on my report.</p> <p>22 Q. Well, how does the FDA take action for</p> <p>23 adulterated product, then, for product that had</p> <p>24 already been sold if nothing is adulterated until</p> <p>25 they issue a warning letter?</p>

<p>Page 206</p> <p>1 A. FDA can ask for recalls of products that 2 are objectionable for various reasons. You 3 mentioned examples yourself. But it doesn't mean 4 that FDA is making an adulteration charge. That's a 5 separate issue. 6 Q. So according to you, adulteration can only 7 exist if the FDA issues a warning letter? 8 A. I would say an adulteration charge is a 9 regulatory determination by FDA that is very 10 carefully considered. Even a warning letter doesn't 11 necessarily mean, you know, an adulteration charge. 12 It's really a signal to a company that they need to 13 focus a little bit more on improving their GMPs. 14 All I'm saying is that Teva products were 15 not adulterated at the time of the recall, so Teva 16 never had adulterated product in the U.S. market. 17 Q. Because you are saying the warning letters 18 were not issued to ZHP or Mylan until after Teva's 19 recalls? 20 A. Yes. If somebody wants to make an 21 adulteration claim here, it seems to me it would 22 occur then, or when FDA set limits and a product was 23 above those limits. The FDA -- oh. 24 Q. So all the -- 25 A. FDA could have set limits that would have</p> <p>Page 207</p> <p>1 let the Teva product be okay. It was just an 2 uncertainty there. But because FDA thought the 3 limits were unacceptably high, without a limit being 4 set, Teva and FDA agreed that these products should 5 come off the market, first ZHP-containing product 6 and then the Mylan product. 7 Q. Uh-huh. 8 A. And then Teva decided not to reenter the 9 market at all. 10 So Teva never had an adulterated product 11 for any of its four valsartan-containing products in 12 the U.S. market. 13 Q. Uh-huh. So from 2012 on, assume all of 14 Teva's products had nitrosamines in it leading up to 15 the recall. You are saying all of that product 16 cannot be considered adulterated? 17 A. It was not adulterated -- 18 Q. Uh-huh. 19 A. -- according to an FDA regulatory 20 determination. 21 Q. Uh-huh. The FDA found that the API that 22 Teva was using that entire time was adulterated, 23 though, correct? 24 A. When do you say that occurred? 25 Q. Well, you tell me. It's in the 483s that</p>	<p>Page 208</p> <p>1 you cite in your report, sir. 2 A. Is it? I don't recall FDA making an 3 adulteration claim in the 483s. Can you show me 4 that? 5 Q. In the warning letters, I apologize. In 6 the warning letters the FDA said that Mylan and 7 ZHP's API was adulterated, correct? 8 A. Yes. I mean, you are reiterating my 9 claim. That's a point at which FDA could be said to 10 have determined a charge of adulteration. 11 Q. Uh-huh. So -- 12 A. And that is a very carefully considered 13 charge. 14 Q. All right. So if I am selling a product 15 starting today, and it contains rat poison, I can 16 keep selling that and keep selling it until the FDA 17 issues me a warning letter, correct? 18 A. No. I think your hypothetical, it needs 19 to be refined for this particular case. There is an 20 impurity, an impurity that we have already talked 21 about is undesirable. It's part of that cohort of 22 concern. 23 But it can have a limit set on it such 24 that the product is safe and effective and of good 25 quality. FDA did not do that until December 2018.</p> <p>Page 209</p> <p>1 But FDA still had the concern that the levels were 2 too high, so they worked with Teva to recall all 3 product. 4 This is separate from a determination of 5 adulteration. The only time I have ever seen 6 adulteration raised in this matter is when FDA sent 7 those warning letters, as you say, to ZHP and Mylan. 8 Q. If not adulterated, what would you call 9 all of Teva's products prior to the FDA's issuance 10 of warning letters to ZHP and Mylan? 11 A. I would call them AB-rated and of good 12 value to the consumer. 13 Q. Even if they contained genotoxic 14 impurities above any limit that was ever set to the 15 present? 16 A. Well, you are getting to the core issue in 17 this matter. 18 First of all, my claim is, and I state it 19 in my report, they were AB-rated. They were 20 pharmaceutically equivalent. They were 21 bioequivalent. They were not misbranded. They had 22 the appropriate labeling relative to the Novartis 23 reference listed drug. 24 Now, if you have an impurity that comes to 25 light, it's a very low-level impurity, it was</p>
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<p style="text-align: right;">Page 210</p> <p>1 unexpected, there are not analytical procedures to 2 adequately measure it, it all of a sudden comes to 3 life, does that make the product worthless? No. It 4 makes the product really fine until FDA and the 5 companies sort through what the appropriate limits 6 should be. 7 Teva didn't do anything wrong. They were 8 making good product at their Malta and Jerusalem 9 facilities. And then FDA comes up with a limit. So 10 then you can say, okay, well, products in the 11 marketplace shouldn't have nitrosamine impurities 12 above that limit. And before all that occurred, 13 Teva had removed all product from the market. 14 Q. Uh-huh. Are you familiar with the FDA's 15 actions against Ranbaxy concerning generic Lipitor? 16 MS. LOCKARD: Outside the scope. 17 THE WITNESS: You know, I could probably 18 be reminded of it, and please do if you think it 19 would be helpful -- if you think it would be 20 helpful, please remind me of that. 21 BY MR. STANOCH: 22 Q. Sure. I'll mark Exhibit 12. 23 (Whereupon, Exhibit 12 was marked for 24 identification.) 25</p>	<p style="text-align: right;">Page 212</p> <p>1 MS. LOCKARD: It is 12:45 here. I don't 2 know, how long have been we been on the record, 3 Ms. Videographer, can you say? 4 MR. HARKINS: Two hours since the last 5 break. 6 MS. LOCKARD: Two hours since the last 7 break, so let's ask the questions about this, and 8 then -- 9 THE VIDEOGRAPHER: An hour 35 since the 10 last break. 11 MS. LOCKARD: You need a new watch. 12 BY MR. STANOCH: 13 Q. Let me know when you can see this exhibit, 14 sir. I'm trying to screen-share now, if that helps 15 as well. 16 A. Okay. I see the screen share. 17 Q. All right. And you see this is a 18 Department of Justice announcement, May 13, 2013? 19 A. Yes, I do see this, and I'm familiar with 20 this fine. 21 Q. Right. And you are familiar that the DOJ 22 fined Ranbaxy, a generic drug manufacturer, 500 23 million relating to cGMP violations and false 24 statements? 25 A. Yes, I do see that.</p>
<p style="text-align: right;">Page 211</p> <p>1 BY MR. STANOCH: 2 Q. Unfortunately, I don't think it's in your 3 binder, but it's relatively short. Let me know when 4 you can see it. 5 A. I think it's coming to me; is that right? 6 MS. LOCKARD: It's not in the binder, so 7 it's only on video screen. 8 THE WITNESS: And I don't see it on the 9 video screen yet. 10 (Whereupon, a brief discussion off the 11 record.) 12 MR. STANOCH: What are you whispering to 13 your counsel about, Doctor? 14 MS. LOCKARD: He asked me to remind him of 15 your name, and I said Stanoch. 16 THE WITNESS: I'm sorry. I had a senior 17 moment. 18 MR. STANOCH: Oh, it's okay, Doctor. I 19 wasn't going to call you out before, and I apologize 20 I did now. It's a long day. 21 MS. LOCKARD: You are right. I should not 22 be whispering. I should have done it louder. 23 MR. STANOCH: It's a -- 24 THE WITNESS: Well, I apologize, too. I 25 may be getting hypoglycemic.</p>	<p style="text-align: right;">Page 213</p> <p>1 Q. Right. And can you still see it? 2 A. I do see it, yes, thank you. 3 Q. Oh, good. I just wanted to make sure you 4 were able to look at it. And you can look at this 5 document all you want, sir, but the issue here is 6 Ranbaxy, I think, was making generic Lipitor, and it 7 was found to contain pieces of glass, right? 8 A. I would have to read more closely to see 9 the pieces of glass, but I'll take your word for it. 10 Go ahead. 11 Q. Okay. And so would you call generic 12 Lipitor that contained pieces of glass AB-rated? 13 A. Well, we're getting into what causes the 14 FDA to remove an AB rating. An AB rating relates to 15 the review process. So, yes, I would say it's 16 AB-rated. 17 Now, after it's in the market and you find 18 something objectionable or it fails a specification 19 or it's not in conformance with GMPs, it needs to be 20 withdrawn from the market. 21 Q. So would you -- 22 A. And that's what happened here. 23 Q. So would you consider Ranbaxy's generic 24 Lipitor that contained pieces of glass adulterated 25 prior to the date of its guilty plea?</p>

<p style="text-align: right;">Page 214</p> <p>1 A. It's not my decision. It's an agency 2 decision. Did the agency make a judgment of 3 adulteration? 4 Q. Well, that's what I'm asking you, sir. 5 A. I don't see it here. If you can point it 6 out to me, I would be glad to offer an opinion. 7 Q. Uh-huh. It says right there -- 8 A. And I don't -- 9 Q. -- in the first paragraph about the 10 "distribution of certain adulterated drugs." 11 A. Yes, adulterated drugs, okay. So there 12 the agency is making a decision that the drugs were 13 adulterated. 14 Q. Right. And if you look on, you know, the 15 next page here, "Ranbaxy USA admitted to introducing 16 into interstate commerce certain batches of 17 adulterated drugs that were produced at Paonta Sahib 18 in 2005 and 2006." You see that? 19 A. Wait a minute. I'm trying to catch up 20 with where you are reading. What paragraph are you 21 in? 22 Q. Second full paragraph of the second page. 23 A. Oh. Yes, I see that. And your question, 24 I'm sorry, is? 25 Q. Right. So you see here, right, that</p>	<p style="text-align: right;">Page 216</p> <p>1 questions. 2 Q. Right. The FDA said at a later point that 3 the drugs you had been selling since 2005 were 4 adulterated, right? 5 A. FDA can make a certain decision in time. 6 But in this case, FDA made the decision when it 7 issued the warning letters for ZHP and Mylan. 8 Q. Right. And it said in that decision that 9 the valsartan API that you have been making up until 10 this point is adulterated, correct? 11 A. No, I'm not agreeing with that. 12 Q. So -- 13 A. I'm saying FDA had -- I'm saying Teva had 14 recalled all product before the agency determination 15 of adulteration. 16 Q. So the fact that Teva was selling product 17 that the FDA later said contained adulterated API, 18 you are saying that has no effect on whether or not 19 Teva was selling adulterated products? 20 A. You know, I think we're confusing a lot of 21 issues here. First of all, we have to look at the 22 warning letters to ZHP and Mylan. And I'm glad to 23 discuss those if you want to give them to me as 24 exhibits. 25 But FDA made the general statement that</p>
<p style="text-align: right;">Page 215</p> <p>1 Ranbaxy admitted that it was selling batches of 2 adulterated drugs produced at a facility in 2005 and 3 2006, right? 4 A. Yes. 5 Q. And that is, what, seven or eight years 6 prior to its guilty plea per this notice of 7 May 13th, 2013, right? 8 A. I'm trying to stay up with your dates. 9 Okay. Yes, I see the dates you are emphasizing. 10 Q. Right. So Ranbaxy was pleading guilty 11 that it was selling adulterated products for nearly 12 ten years prior to the institution of regulatory 13 action against it, right? 14 A. Yes. I see that. 15 Q. But it sounds like you are telling me that 16 you would not consider any of that Ranbaxy product 17 adulterated up and until the point where the FDA 18 actually issued a warning letter; is that right? 19 A. No, the way I read this, I think Ranbaxy 20 stated their drugs were adulterated in 2005, 2006, 21 and that's an agency determination. 22 Q. Right. They retrospectively made that 23 determination? 24 A. Well, I don't know if it is retrospective 25 or not, but -- go on. I'll try to answer your</p>	<p style="text-align: right;">Page 217</p> <p>1 products -- or drug substances produced at ZHP were 2 adulterated within the meaning of the act because of 3 GMP violations. I would have to see it. I'm not 4 even sure it mentions nitrosamines -- 5 Q. Uh-huh. Okay. 6 A. -- or the fact that the products 7 containing nitrosamines were adulterated. 8 Q. Okay. Let's take out nitrosamines. So 9 Teva selling valsartan that contained API that the 10 FDA eventually said was adulterated because of cGMP 11 violations has no impact on whether Teva's product 12 was adulterated? 13 A. Well, I would -- is it possible to look at 14 the ZHP warning letter? 15 Q. If you have a copy there, sir, go ahead. 16 I don't know if I have it. 17 A. It's not in your exhibits? 18 MS. LOCKARD: We have a copy of it. 19 THE WITNESS: I don't think I cited it in 20 my report. I don't think it's in a -- 21 MS. LOCKARD: There is no question 22 pending, so you don't have to answer. 23 BY MR. STANOCH: 24 Q. Uh-huh. Did you cite the ZHP warning 25 letter from the FDA in your report, sir?</p>

<p style="text-align: right;">Page 218</p> <p>1 A. I don't think it's in my materials cited. 2 I don't recall seeing it there. And that's true 3 also for Mylan. So -- 4 Q. Okay. Well, we will figure that out. 5 Let's put all this aside for now, and we can come 6 back to it, but we want to go -- 7 (Whereupon, a brief discussion off the 8 record.) 9 THE VIDEOGRAPHER: Okay. We are going off 10 the record. The time is 12:51. 11 (Whereupon, a brief recess was taken.) 12 THE VIDEOGRAPHER: Okay. We are coming 13 back on the record. The time on the video monitor 14 is 1:34. Please begin. 15 BY MR. STANOCH: 16 Q. Welcome back, Dr. Williams. 17 A. Thank you, Mr. Stanoch. 18 Q. During our lunch break did you speak with 19 anyone besides your counsel there with you in San 20 Francisco? 21 A. No, I didn't. 22 Q. Did you text or e-mail anybody about your 23 testimony today? 24 A. No, not at all. 25 Q. And did you review any documents?</p>	<p style="text-align: right;">Page 220</p> <p>1 trying to market in the U.S. a new generic 2 combination product that includes valsartan? 3 MS. LOCKARD: Objection. Foundation. 4 THE WITNESS: Was that a question, 5 Mr. Stanoch? 6 BY MR. STANOCH: 7 Q. Yes. Did your opinions in any way relate 8 to the fact that Teva is trying to market in the 9 U.S. a new generic combination product that includes 10 valsartan? 11 A. No, not at all. 12 Q. Uh-huh. Uh-huh. Do you think it would be 13 pertinent to your opinions in this case if you were 14 to eventually evaluate the testing and other 15 parameters that Teva is applying for its new generic 16 combination product that includes valsartan that it 17 may introduce in the U.S.? 18 MS. LOCKARD: Objection. Confusing. 19 THE WITNESS: No, I can't see how that 20 would have any impact on my report -- 21 BY MR. STANOCH: 22 Q. Uh-huh. 23 A. -- and it certainly wouldn't change my 24 opinions. 25 Q. Well, would you like to know what testing</p>
<p style="text-align: right;">Page 219</p> <p>1 A. We did not. 2 Q. Okay. Thank you. 3 Could you describe for me what it means 4 that your expert report is only for class 5 certification and not for liability? 6 A. My understanding is the liability 7 litigation will occur later, and right now we're 8 looking at class certification that relates to 9 economic loss for individual plaintiffs and also 10 large payors. 11 Q. Uh-huh. Right. And prior to the break we 12 were talking a little bit about the Teva recalls, 13 and I think you said that Teva had recalled all of 14 its valsartan product from the market and has not 15 reintroduced it, correct? 16 A. Yes, that's true, Mr. Stanoch. 17 Q. Okay. Are you aware of whether Teva has 18 been undertaking to introduce a new generic 19 combination product that includes valsartan? 20 A. You know, I believe in the course of some 21 of my research or discussions with counsel, I did 22 hear that. But I know very little about what they 23 are doing, and it's certainly not in my report. 24 Q. Okay. I was going to say, do your 25 opinions in any way relate to the fact that Teva is</p>	<p style="text-align: right;">Page 221</p> <p>1 Teva is doing of this new product under development 2 for nitrosamines? 3 A. I would always be interested in what Teva 4 is doing because of their sophistication as a 5 pharmaceutical company, but it doesn't relate to my 6 report and it doesn't impact my opinions. 7 Q. Uh-huh. But if Teva is testing for 8 nitrosamines now for a new product in ways that were 9 available to it prior to 2018, that would be 10 pertinent, would it not? 11 MS. LOCKARD: Objection. Speculation. 12 Foundation. 13 THE WITNESS: Well, the way I would try to 14 couch it in terms of my report is Teva should be 15 following the 2021 guidance on nitrosamine 16 impurities, and how they deal with those 17 recommendations from FDA, as I say, would be of 18 scientific interest to me, but not pertinent to my 19 report. 20 BY MR. STANOCH: 21 Q. That's fair. Do you know whether Teva is 22 following the FDA 2021 guidance on nitrosamine 23 impurities regarding its development of a new 24 valsartan combination product for the U.S. market? 25 A. Do I know what about that? I'm sorry.</p>

<p style="text-align: right;">Page 222</p> <p>1 Q. Do you know whether Teva -- or strike 2 that. 3 Do you know how, if at all, Teva is 4 following the FDA 2021 guidance on nitrosamine 5 impurities regarding Teva's development of a new 6 valsartan combination product for the U.S. market? 7 A. No, I have no idea, and I'm sure Teva 8 might regard that as confidential information. 9 Q. Uh-huh. You reference throughout your 10 report, and we can look at particular paragraphs, 11 pharmaceutically equivalent and bioequivalent; is 12 that right? 13 A. Yes, I do speak to those points, 14 Mr. Stanoch. 15 Q. Okay. And we can look -- you can look at 16 any paragraph you like, but you can look at, say, 17 Paragraph 60, where you mention both these terms, if 18 that's helpful. 19 A. Okay. Thank you. I'll go to Paragraph 20 60. Okay. And that's on page 19? 21 Q. Yes. Are you there? 22 A. Yes, I am, sir. 23 Q. Okay. Now, what do you mean by 24 "bioequivalent," as you use the term in your report? 25 A. Well, it's a requirement for a generic</p>	<p style="text-align: right;">Page 224</p> <p>1 equivalence means both pharmaceutically equivalent 2 and bioequivalent. 3 Q. Uh-huh. Isn't it true, Doctor, that 4 therapeutic equivalence includes pharmaceutical 5 equivalence, bioequivalence, as well as having the 6 same clinical effect and safety profile? 7 A. No, I wouldn't add that, Mr. Stanoch. I 8 think the purpose of the bioequivalence study is to 9 say the bioequivalence study substitutes for 10 assessment of clinical safety and efficacy. 11 Q. Okay. Let's look at the next exhibit. 12 Stand by. 13 This will be Exhibit 13. It's Tab 10 in 14 your binder, sir. 15 (Whereupon, Exhibit 13 was marked for 16 identification.) 17 BY MR. STANOCH: 18 Q. Let me know when you are there. 19 A. Okay. I'm looking at the Orange Book 20 preface. 21 Q. Right. This is a copy of the Orange Book 22 preface, correct? 23 A. Yes. 24 Q. And you are certainly familiar with the 25 Orange Book, I take it, right?</p>
<p style="text-align: right;">Page 223</p> <p>1 manufacturer to show bioequivalence between their 2 proposed product and the reference listed drug. And 3 it's expressed in law and regulations as an absence 4 of difference in terms of the rate and extent of the 5 generic product compared to the reference listed 6 drug. 7 Q. What do you mean by the term 8 "pharmaceutically equivalent" as used in your 9 report? 10 A. Well, if you, again, look at the law and 11 regulations, "pharmaceutical equivalence" means the 12 same active ingredient; different impurities, 13 possibly; the same dose form; the same strength; and 14 the same route of administration. 15 So the two terms together, if they are met 16 by a generic manufacturer, allow the agency to 17 declare that the products are therapeutically 18 equivalent, and if those requirements are satisfied, 19 among other things, then FDA can give an AB rating 20 in the Orange Book. 21 Q. And then I think in this paragraph, the 22 second sentence, you explain what you mean by 23 therapeutic equivalence; is that right? 24 A. Yes, and I may have gotten a little bit 25 ahead of your questioning, but therapeutic</p>	<p style="text-align: right;">Page 225</p> <p>1 A. Yes. 2 Q. And what is the Orange Book? 3 A. It's an FDA publication entitled Approved 4 Drug Products with Therapeutic Equivalence 5 Evaluations. And then after that, we always say, 6 "commonly referred to as the Orange Book." And the 7 reason for that, it is an orange book. 8 I even know how it came to have the color 9 orange. It was actually created around the time of 10 Halloween, so that's why it's colored orange. 11 But it lists the FDA-approved products 12 approved under the NDA/ANDA system. 13 I'll stop there, Mr. Stanoch. 14 Q. Okay. I appreciate that answer, including 15 the color commentary on the Orange Book, Doctor. 16 If you can turn to the section 1.2, 17 "Therapeutic Equivalence-Related Terms." 18 A. Yeah, I'm getting there. 1.1. 19 Okay. I'm there. 20 Q. And this section talks about certain 21 terms. Do you see that? 22 A. I do. 23 Q. And one of those terms is "therapeutic 24 equivalents," correct? 25 A. Yes. Under 1.2.</p>

<p>Page 226</p> <p>1 Q. Yes. And could you just read us that 2 first paragraph there for "Therapeutic Equivalents," 3 where it says, "Approved drug products are"? 4 A. "Are drug products in identical dosage 5 forms and route(s) of administration" and "contain 6 identical amounts" -- 7 Q. Oh, oh. Oh, oh, oh, oh, Doctor. I'm 8 sorry to stop you. I was trying to direct you to 9 the paragraph that is there for "Therapeutic 10 Equivalents." Do you see that a little down? 11 A. Oh, sure. Down below? 12 Q. Yes. And just that -- it's three lines, 13 the first paragraph. Do you see that? 14 A. Yeah, where it says, "Approved drug 15 products"? 16 Q. Yes, sir. Could you just read that 17 paragraph? 18 A. Sure. "Approved drug products are 19 considered to be therapeutic equivalents if they are 20 pharmaceutical equivalents for which bioequivalence 21 has been demonstrated, and they can be expected to 22 have the same clinical effect and safety profile 23 when administered to patients under the conditions 24 specified in the labeling." 25 Q. Right. And that second clause there that</p>	<p>Page 228</p> <p>1 look through it, that you don't mention anything 2 about a therapeutic equivalent having the same 3 clinical effect and safety profile. 4 A. Well -- 5 Q. Why did you leave that part out? 6 A. You know, Mr. Stanoch, I have to say, it's 7 an unimportant question. I think everybody knows 8 that if you show pharmaceutical equivalence and 9 bioequivalence, you then are allowed to have the 10 same labeling as the reference listed drug, 11 substantively, and this means you will have the same 12 clinical effect and safety. 13 I don't know why you are questioning my 14 words in my report, so perhaps you can explain that 15 at the right time. 16 Q. Well, we can agree that your Paragraph 60 17 does not include the words "same clinical effect and 18 safety profile," right? 19 A. No, and it's certainly understood, and I 20 think any reasonable person would understand, what I 21 meant when I talked about pharmaceutical equivalence 22 and bioequivalence. 23 Q. So show me in Paragraph 60 where those 24 words appear then, Doctor. 25 A. Which words?</p>
<p>Page 227</p> <p>1 you read, that is something that is absent from your 2 characterization of therapeutic equivalence in 3 Paragraph 60 of your report, correct? 4 A. Yes. I think -- my hope -- everything is 5 aligned and in agreement, but that is what I mean 6 when I made those statements in Paragraph 60. 7 Q. And earlier I think you said that same 8 clinical effect and safety is not part of 9 therapeutic equivalence. Are you changing your 10 testimony that you agree that a therapeutic 11 equivalent can be expected to have the same clinical 12 effect and safety profile when administered to 13 patients under the conditions specified in the 14 label? 15 A. Well, I think, without quibbling with you, 16 Mr. Stanoch, what I was trying to say is in terms of 17 the application process, the demonstration is the 18 end of the sentence. And if those two types of 19 equivalence are demonstrated, then, as you want to 20 go on and say, they can be expected to have the same 21 clinical effect and safety. But in terms of the 22 concept of therapeutic equivalence, it stops with 23 demonstration. 24 Q. Well, because I don't see anywhere in your 25 report, doing a word search, and you can certainly</p>	<p>Page 229</p> <p>1 Q. "Same clinical effect and safety profile." 2 A. I don't say that. That's what therapeutic 3 equivalence means. 4 Q. Uh-huh. 5 A. "Therapeutic equivalence" are the same 6 words as "same clinical effect and safety profile." 7 Q. Uh-huh. Right. And those words do not 8 appear anywhere in your report, though? 9 A. "Therapeutic equivalence" appears there, 10 and it means the same thing as identical safety and 11 efficacy outcomes. That's what it means to have the 12 same labeling as the reference listed drug. 13 Q. Well, Doctor, I want to make sure we're 14 not talking past each other. I'm looking at your 15 Paragraph 60, and it says, "Therapeutic equivalence 16 means that the drug is pharmaceutically equivalent 17 and bioequivalent for the same use," period; is that 18 right? 19 A. Mr. Stanoch, I just really am not 20 following your line of questioning. Can you be more 21 clear? 22 Q. Oh, absolutely, Doctor. I'm looking at 23 the words you wrote. 24 A. I think I'm -- 25 Q. So let's look at Paragraph -- go ahead.</p>

<p>Page 230</p> <p>1 A. Mr. Stanoch, let me finish my answer. 2 Q. Please. 3 A. I think I am perfectly clear here. 4 Anybody would understand what I'm saying who 5 understands generic substitution. Now, what is it 6 about my statement or my words that you are not 7 getting? 8 Q. I'm getting it about the words that are 9 not there, Doctor, that's my first step. I'm 10 looking at Paragraph 60. Can we agree -- 11 A. Well -- 12 Q. Let me finish my question, Doctor, I let 13 you finish your answer, please. 14 Your Paragraph 60, when you're defining 15 therapeutic equivalence, you say, "Therapeutic 16 equivalence means that the drug is pharmaceutically 17 equivalent and bioequivalent for the same use," 18 period, correct? 19 A. I don't think you are reading my words 20 correctly. 21 Q. Well, you turn to Paragraph 60, 22 Dr. Williams. 23 A. Would you please try to read my words 24 correctly? 25 Q. Why don't you read Paragraph 60 to me,</p> <p>Page 231</p> <p>1 Dr. Williams? 2 A. All right. I'll be glad to. "Generic 3 drugs that are pharmaceutically equivalent and 4 bioequivalent to the" reference listed drug and "are 5 deemed therapeutically equivalent and are 6 interchangeable with the" reference listed drug. 7 Now, what part of that don't you understand? 8 Q. Please keep reading, Doctor. 9 A. "Therapeutic equivalence means" "the drug 10 is pharmaceutically equivalent and bioequivalent for 11 the same use." We're talking about the labeling. 12 In other words, if you're pharmaceutically 13 equivalent and bioequivalent, you get to use the 14 same labeling as the referenced listed drug. If you 15 have the same labeling, you will necessarily have 16 the same clinical effect and safety profile. 17 I think these words are almost 18 self-evident, and I really wonder why I haven't been 19 clear about it with you. 20 Q. Doctor, I'm asking you to tell us where in 21 Paragraph 60 you write that therapeutic equivalence 22 can be expected to have the same clinical effect and 23 safety profile? 24 A. I don't write it. I never said I did. 25 Q. And you don't write it anywhere in your</p>	<p>Page 232</p> <p>1 report, correct? 2 A. I don't need to write it in my report. 3 It's not pertinent. It's unnecessary. 4 Q. Uh-huh. And does valsartan containing 5 nitrosamine impurities have the same safety profile 6 as valsartan that do not have nitrosamine 7 impurities? 8 A. Impurities are not a determinant of either 9 pharmaceutical equivalence or bioequivalence, and 10 that would include nitrosamine impurities. 11 Q. We're talking therapeutic equivalence now, 12 aren't we? 13 A. I don't know. Is that your question? 14 Q. That's what we have been talking about, 15 Dr. Williams. Let me ask it again. 16 Do you believe valsartan containing 17 nitrosamines have the same safety profile as 18 valsartan that does not contain any nitrosamines? 19 A. Okay. 20 MS. LOCKARD: Objection. Form of the 21 question. Vague. 22 THE WITNESS: That is a different 23 question. And I would say, with appropriate limits, 24 yes, the answer to your question is yes. 25</p> <p>Page 233</p> <p>1 BY MR. STANOCH: 2 Q. Well, what do you mean by "appropriate 3 limits"? 4 A. Well, for example, the interim limits that 5 FDA set in December 2018 for -- 6 Q. In absence of those limits, do you believe 7 valsartan containing nitrosamines has the same 8 safety profile as valsartan that does not contain 9 any nitrosamines? 10 A. Are you asking my personal opinion? Or 11 are you asking me as part of my report? 12 Q. You are the one opining on therapeutic 13 equivalence, Doctor, so I'm asking you, both in your 14 opinions and in your personal knowledge. 15 A. I would say it would have the same 16 therapeutic outcome in terms of safety and efficacy. 17 If somebody wants to give data that suggests 18 otherwise, the FDA could look at that data. 19 Q. Uh-huh. You are talking about therapeutic 20 outcomes, you are referring to whether the drug 21 works for its intended purpose, right? 22 A. I would say when we look at these words, 23 yes, we are talking about the valsartan molecule. 24 Q. Right. And still the issue we're trying 25 to get at here, Doctor, is: In the absence of</p>
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<p style="text-align: right;">Page 234</p> <p>1 interim limits, do you believe valsartan containing 2 nitrosamines, which you have agreed is part of the 3 cohort of concern, has the same safety profile as 4 valsartan that does not contain nitrosamines? 5 A. Well, let's back up a little bit. First 6 of all, we understand that the impurity profile can 7 be different in the drug substance of the generic 8 compared to the reference listed drug. And there 9 could be many, many impurities in those two drug 10 substances with unknown pharmacologic effects. 11 When you see a particular impurity of 12 concern, you would like to put a limit on it, 13 including whether it's a genotoxic impurity or not. 14 That's the whole idea behind reporting, 15 identification, and qualification. 16 I think nitrosamine impurities here are 17 part of the general approach to impurity handling. 18 So I would say if nitrosamine impurities are handled 19 the way other impurities are handed in the world of 20 generic substitution, yes, you would get the same 21 safety and efficacy outcomes. 22 Q. What if they are not handled in the way 23 other impurities are handled? 24 A. Well, if I don't -- can you be more 25 specific in your question in terms of how they would</p>	<p style="text-align: right;">Page 236</p> <p>1 commonly found in foodstuffs and they can be allowed 2 in chemically synthesized drugs at certain levels. 3 And the goal here of this whole effort really has 4 been to identify them and make sure they do not 5 exceed those levels. 6 BY MR. STANOCH: 7 Q. Would you advise patients to keep taking 8 recalled valsartan products? 9 MS. LOCKARD: Objection. Speculation. 10 Outside the scope. 11 THE WITNESS: Well, that seems a very odd 12 question since they were recalled. Is that a 13 hypothetical? 14 BY MR. STANOCH: 15 Q. Well, we are just trying to say what you 16 would do with a patient, Doctor. And by the way, 17 you are a doctor, correct? 18 A. That's right. 19 Q. You have an active medical license, 20 correct? 21 A. I do not. 22 Q. You do not. When was your medical license 23 last active? 24 A. In 1990. I stopped treating patients 25 clinically when I went to FDA in 1990.</p>
<p style="text-align: right;">Page 235</p> <p>1 be handled differently? 2 Q. Sure. Prior to June 2018, assume there is 3 valsartan that contains nitrosamines and valsartan 4 that does not contain nitrosamines. Do they have 5 the same safety profile? 6 A. We just don't know that. 7 Q. So then how -- 8 A. I mean, for all I know, the valsartan drug 9 substances that contain nitrosamine may have been at 10 perfectly safe levels. I just don't know that. 11 Q. Uh-huh. 12 A. FDA finally decided they need to be below 13 certain interim limits. But even there, I think FDA 14 would say the risk was very low and that their 15 limits were very conservative. So you are asking a 16 question that would be very difficult to answer. 17 Q. Uh-huh. Well, in the real world, Doctor, 18 right, if you go to a patient and you say to the 19 patient, do you want this valsartan that contains 20 nitrosamines or do you want this valsartan that does 21 not contain nitrosamines, what do you advise your 22 patient? 23 MS. LOCKARD: Objection. Outside the 24 scope of his expertise. 25 THE WITNESS: I would say nitrosamines are</p>	<p style="text-align: right;">Page 237</p> <p>1 Q. Uh-huh. Uh-huh. And would you advise a 2 patient, if given the choice, to take valsartan that 3 contained nitrosamines or valsartan that did not 4 contain nitrosamines? 5 MS. LOCKARD: Objection. Outside the 6 scope of his expert report and opinions. 7 THE WITNESS: You know, it's a 8 hypothetical. I'm going to give you an answer that 9 may not seem appropriate. 10 But I worked once with a very 11 sophisticated chemist at FDA who said you get more 12 impurities in the back of a Washington, D.C., bus 13 than you will ever get from your medicines. 14 So, you know, it's a question of risk, 15 relative risk, severity of risk, and I just don't 16 think I can answer your question. 17 BY MR. STANOCH: 18 Q. You have a -- oh, sorry. Go ahead. 19 A. I would say to patients, FDA will control 20 impurities within the -- nitrosamine impurities 21 within your medical products appropriately in 22 accordance with the new guidance. 23 Q. Uh-huh. Prior to the FDA guidance in 24 December 2018, right, would you advise a patient to 25 take valsartan with nitrosamines or the valsartan</p>

<p style="text-align: right;">Page 238</p> <p>1 without nitrosamines?</p> <p>2 A. Well, let me point out that FDA told</p> <p>3 people to keep on taking their valsartan products</p> <p>4 before the interim limits were set.</p> <p>5 Q. And that was so they don't drop dead of a</p> <p>6 heart attack, correct?</p> <p>7 MS. LOCKARD: Objection. Speculation.</p> <p>8 THE WITNESS: I would not say that it way.</p> <p>9 BY MR. STANOCH:</p> <p>10 Q. Right. Because they did not want to go</p> <p>11 off your medication for hypertension abruptly until</p> <p>12 you had a substitute; isn't that right, Doctor?</p> <p>13 A. Well, they did not want people to abruptly</p> <p>14 stop their medicines containing valsartan.</p> <p>15 Q. Absolutely correct. But don't you think</p> <p>16 the idea there was: Don't abruptly stop, but you</p> <p>17 should probably get a different valsartan product or</p> <p>18 other substitute as soon as you can?</p> <p>19 MS. LOCKARD: Objection. Speculation.</p> <p>20 Outside the scope of his expert testimony and this</p> <p>21 report.</p> <p>22 THE WITNESS: I'll just stand by what FDA</p> <p>23 said. They said, don't -- you know, the risk here</p> <p>24 is very low. The recall classification risk was</p> <p>25 low. And they were saying, don't stop your</p>	<p style="text-align: right;">Page 240</p> <p>1 Can you imagine how many patients you</p> <p>2 would have to study to see a difference even if it</p> <p>3 existed?</p> <p>4 Q. Let's talk about today, right. The FDA</p> <p>5 limits for nitrosamines exist today, right?</p> <p>6 A. Yes.</p> <p>7 Q. Does a valsartan drug that contains</p> <p>8 nitrosamines above those limits have the same safety</p> <p>9 profile as a valsartan drug with nitrosamines below</p> <p>10 those limits?</p> <p>11 A. Far as I know, they have the same safety</p> <p>12 and efficacy outcomes.</p> <p>13 Q. So then what is the point of the interim</p> <p>14 limits, then, which say, if you have more than this,</p> <p>15 you can't sell it?</p> <p>16 A. You have to set some kind of limits.</p> <p>17 That's what an impurity is. An impurity needs a</p> <p>18 limit.</p> <p>19 Q. But you just said, Doctor, that a</p> <p>20 valsartan product with nitrosamines above the limits</p> <p>21 as they exist today is just as safe as one that has</p> <p>22 nitrosamines below the limit, didn't you?</p> <p>23 A. I have no understanding that it has a</p> <p>24 different safety profile in terms of any kind of</p> <p>25 risk.</p>
<p style="text-align: right;">Page 239</p> <p>1 valsartan medicines abruptly under these</p> <p>2 circumstances.</p> <p>3 BY MR. STANOCH:</p> <p>4 Q. Uh-huh. All right. So let's go back to</p> <p>5 the safety profile one more time, Doctor. You are</p> <p>6 not going to tell us whether you think a valsartan</p> <p>7 with nitrosamines might have a different safety</p> <p>8 profile than a valsartan without nitrosamines?</p> <p>9 A. I absolutely don't know, and to answer</p> <p>10 that question would be a very difficult comparative</p> <p>11 clinical trial.</p> <p>12 Q. Uh-huh. Well, let's say right now with --</p> <p>13 let's say today --</p> <p>14 MS. LOCKARD: Wait. Hold on a minute.</p> <p>15 Let him --</p> <p>16 BY MR. STANOCH:</p> <p>17 Q. Oh, go ahead, Doctor.</p> <p>18 A. And if you think about what it would take</p> <p>19 to answer that question, imagine a comparative</p> <p>20 clinical trial where you have patients randomized</p> <p>21 between two valsartan-containing products, one with</p> <p>22 one limit set by FDA and one with no limits before</p> <p>23 FDA set limits. Imagine the outcome of that</p> <p>24 clinical trial. I think it would be very hard to</p> <p>25 see a difference.</p>	<p style="text-align: right;">Page 241</p> <p>1 Q. If not for safety, Doctor, then why is the</p> <p>2 FDA setting limits for nitrosamines in the first</p> <p>3 place?</p> <p>4 A. They need to set a limit for the impurity,</p> <p>5 and they base it on that M7 guidance in terms of how</p> <p>6 you set limits for genotoxic impurities.</p> <p>7 Q. Which is --</p> <p>8 A. Remember, it's a very difficult decision</p> <p>9 because nitrosamine impurities are present in food</p> <p>10 and foodstuffs and in the environment, in the water.</p> <p>11 And you saw it in the M7 guidance. How do you set</p> <p>12 limits when that kind of impurity is present all</p> <p>13 around us, if you will?</p> <p>14 FDA has to do something. They do it out</p> <p>15 of an abundance of caution. But it doesn't mean</p> <p>16 that something above the limit was therefore toxic.</p> <p>17 Q. You can't sell a product today that is</p> <p>18 above the nitrosamine limits, correct?</p> <p>19 A. Well, I'll generally agree with you, but I</p> <p>20 will also say that in the guidance they say you can</p> <p>21 be above limits under certain circumstances with FDA</p> <p>22 approval.</p> <p>23 Q. Are you aware of any manufacturer who has</p> <p>24 sought FDA approval to sell a product with</p> <p>25 nitrosamines above the now-current limits?</p>

<p style="text-align: right;">Page 242</p> <p>1 A. No, I am not.</p> <p>2 Q. Uh-huh. And you are telling me that the</p> <p>3 FDA limits on nitrosamines have nothing to do with</p> <p>4 the safety of the drug; is that your testimony</p> <p>5 today, sir?</p> <p>6 A. I think they have to do with reducing</p> <p>7 risk, and that is how FDA would state it in terms of</p> <p>8 the M7 guidance and also the nitrosamine guidance.</p> <p>9 Q. Risk of what?</p> <p>10 A. But that risk is very difficult to</p> <p>11 quantify.</p> <p>12 Q. Risk of what?</p> <p>13 A. Risk of whatever a nitrosamine impurity</p> <p>14 might do.</p> <p>15 Q. Uh-huh. What might it do?</p> <p>16 MS. LOCKARD: Objection. Speculation.</p> <p>17 Outside the scope of his opinions.</p> <p>18 THE WITNESS: I'm sorry. Was that a</p> <p>19 question, Mr. Stanoch? I didn't hear it.</p> <p>20 BY MR. STANOCH:</p> <p>21 Q. Yes, sir. What might it do, the risk?</p> <p>22 A. Well, you can see it in the M7 guidance,</p> <p>23 that it has the propensity in certain settings to</p> <p>24 cause cancer.</p> <p>25 Q. Right. Right. The purpose of the FDA's</p>	<p style="text-align: right;">Page 244</p> <p>1 with nitrosamines below the limit or quantified at</p> <p>2 zero?</p> <p>3 MS. LOCKARD: Objection. Outside the</p> <p>4 scope of his opinions.</p> <p>5 THE WITNESS: I'm saying that</p> <p>6 hypothetically that could easily be possible.</p> <p>7 BY MR. STANOCH:</p> <p>8 Q. Uh-huh. Okay. Let's look at the exhibit</p> <p>9 some more. The next paragraph, do you see where it</p> <p>10 reads, "FDA classifies as therapeutically</p> <p>11 equivalent"? Do you see that?</p> <p>12 A. Yes.</p> <p>13 Q. And then it lists a number of criteria</p> <p>14 which the Orange Book says the FDA classifies for</p> <p>15 purposes of therapeutic equivalence, right?</p> <p>16 A. Yes. Are you reading that final paragraph</p> <p>17 on this page?</p> <p>18 Q. Yes, sir. The sentence reads, "FDA</p> <p>19 classifies as therapeutically equivalent those drug</p> <p>20 products that meet the following general criteria";</p> <p>21 do you see that?</p> <p>22 A. Yes, I do, and then it goes one, two,</p> <p>23 three -- I guess the last one is four -- five. It</p> <p>24 continues on, and I think it ends with five.</p> <p>25 Q. Yes, sir. I agree with that.</p>
<p style="text-align: right;">Page 243</p> <p>1 limits currently is because there is a risk, however</p> <p>2 quantified, to a patient if they take a pill that</p> <p>3 has nitrosamines above the limit, right?</p> <p>4 MS. LOCKARD: Objection. That's far</p> <p>5 outside the scope of his opinions. He's not giving</p> <p>6 a causation opinion.</p> <p>7 THE WITNESS: Yeah, I am not definitely</p> <p>8 not getting into causation.</p> <p>9 BY MR. STANOCH:</p> <p>10 Q. I'm not asking you either that, Doctor.</p> <p>11 What we're trying to understand here now is the</p> <p>12 safety profile of a drug that has nitrosamines above</p> <p>13 the limit. And you were telling me, correct me if</p> <p>14 I'm wrong, that it has nothing to do with safety,</p> <p>15 correct?</p> <p>16 A. No, I'm saying I don't know if there is a</p> <p>17 difference between the safety profile of the two</p> <p>18 products.</p> <p>19 Q. So --</p> <p>20 A. It may be exactly the same, and to prove</p> <p>21 that it's different would take a lot of work.</p> <p>22 That's my point.</p> <p>23 Q. Uh-huh. So you are saying that a</p> <p>24 valsartan drug with nitrosamines above the current</p> <p>25 limits may be just as safe as a valsartan product</p>	<p style="text-align: right;">Page 245</p> <p>1 And these are criteria that the Orange</p> <p>2 Book reports that the FDA uses for classifying drug</p> <p>3 products as therapeutically equivalent, correct?</p> <p>4 A. Yes.</p> <p>5 Q. All right. And one of those is Number 5,</p> <p>6 is whether the drug product is "manufactured in</p> <p>7 compliance with Current Good Manufacturing Practice</p> <p>8 regulations," correct?</p> <p>9 A. Yes, I see that.</p> <p>10 Q. And another one is 2(b), which is that the</p> <p>11 drug products "meet compendial or other applicable</p> <p>12 standards of strength, quality, purity, and</p> <p>13 identity"; did I read that correctly?</p> <p>14 A. Yes, you did.</p> <p>15 Q. Right. So for therapeutic equivalence,</p> <p>16 meaning compendial standards alone may not be</p> <p>17 sufficient per the Orange Book's guidance, correct?</p> <p>18 A. That's quite true, because sometimes there</p> <p>19 isn't a compendial standard, so in that case there</p> <p>20 would be a private, FDA-agreed standard.</p> <p>21 Q. Uh-huh. And there may be other examples</p> <p>22 as well, correct?</p> <p>23 A. Well, I don't know what you mean by that.</p> <p>24 I'm thinking of the case where there is no</p> <p>25 compendial standard.</p>

<p style="text-align: right;">Page 246</p> <p>1 Q. Uh-huh. And there may be standards 2 reflected in ICH or other industry guidance, 3 correct? 4 A. No, I wouldn't go there. I'm trying to 5 think of a simple case, that many times FDA doesn't 6 have a monograph for a drug substance or a drug 7 product -- 8 Q. Uh-huh. 9 A. -- in which case, the quality would be 10 controlled with a private specification agreed to 11 with FDA as part of the review process. 12 Q. Uh-huh. This criteria 2(b) does not say 13 anything about the absence of a compendial standard, 14 correct? 15 A. Well, I think it does. It says, "meet 16 compendial or other applicable standards." 17 Q. Uh-huh. 18 A. The other applicable standards would be 19 the private specification agreed to with FDA. 20 Q. Uh-huh. And I think you testified about 21 this earlier, that a manufacturer can agree to 22 different specifications or standards for a drug in 23 consultation with the regulator, right? 24 A. Yeah, I think that's generally part of 25 what I'm saying here.</p>	<p style="text-align: right;">Page 248</p> <p>1 found to be adulterated or otherwise improperly 2 marketed, right? 3 A. Yeah. I think what we're getting at here, 4 too, is the idea that there can be recalls if a 5 product fails its specifications, and that happens 6 all the time, as I stated in my report. That 7 doesn't mean it will be taken out of the Orange Book 8 or its AB rating will be changed. I think that's 9 what we're talking about here. 10 Q. You can put that aside for now. 11 (Whereupon, a brief discussion off the 12 record.) 13 BY MR. STANOCH: 14 Q. Are you aware of whether Teva has a master 15 drug file for valsartan? 16 A. If I understand your question, 17 Mr. Stanoch, are you saying Teva makes its own 18 valsartan? 19 Q. Right. Do you understand Teva to have a 20 drug master file for valsartan? 21 A. Yes, thank you. 22 No, I am not aware of that. I would think 23 it would be possible. 24 Q. Would seeing documents related to Teva's 25 own valsartan DMF be pertinent to you in terms of</p>
<p style="text-align: right;">Page 247</p> <p>1 Q. Then let's flip a few more pages. 2 Unfortunately it's not numbered, Doctor. This is 3 the section that has 1.7, "Therapeutic Equivalence 4 Evaluation Codes." Tell me when you are there. 5 A. Okay. I'm there. 6 Q. And if you look at the first paragraph of 7 that page, it begins in bold, "Every product in the 8 Orange Book is subject at all times to regulatory 9 action." Do you see that? 10 A. Yes, I do, at the very top of the page. 11 Q. And you can read that full paragraph if 12 you like, but I want to direct your attention to the 13 penultimate sentence that begins, "FDA believes that 14 retention"; do you see that? 15 A. Yes, I do see that. 16 Q. Could you just read that sentence, just 17 that sentence, sir? 18 A. "FDA believes that retention of a 19 violative product in the Orange Book will not have 20 any significant adverse health consequences, because 21 other legal mechanisms are available to the Agency 22 to prevent the product's actual marketing." 23 Q. Thank you. And that means, does it not, 24 that just because a drug is listed in the Orange 25 Book, does not mean that it's immune from being</p>	<p style="text-align: right;">Page 249</p> <p>1 whether Teva could have known about nitrosamines 2 forming as part of the API manufacturing process for 3 valsartan? 4 MS. LOCKARD: Objection. Lacks 5 foundation. 6 THE WITNESS: I wouldn't rule it out, but 7 I don't think -- I didn't see any documents like 8 that. 9 BY MR. STANOCH: 10 Q. Uh-huh. Stand by. 11 Could you turn in your report, sir -- it's 12 beginning around Paragraph 120, the first Paragraph 13 120. I think it's around page 41. I don't have the 14 exact copy you have in front of you. 15 A. 120? 16 Q. Yes, sir. 17 A. On page 41? 18 Q. Yes. 19 A. "Doctor Panagos asserts"? 20 Q. Yes. Are you there? 21 A. Yes, I am. 22 Q. Great. And in this subsection, you're 23 rebutting, if you will, opinions offered by 24 Dr. Panagos, correct? 25 A. Yes, I agree.</p>

<p>Page 250</p> <p>1 Q. Right. And why don't you read the first 2 couple sentences for us there in Paragraph 120? 3 A. "Dr. Panagos asserts that the safety and 4 efficacy of a medication must be proven by the 5 manufacturer to the FDA so that the medication may 6 receive approval." I think it's a she. She 7 "further states that this information serves as a 8 warranty for the medication ensuring that it meets 9 the quality standards outlined by" "FDA." 10 Should I stop? 11 Q. You can stop now. 12 A. Okay. 13 Q. And you picked up on part of it. You 14 understand, you know, Dr. Panagos is a female, 15 correct? 16 A. Yes, I see that now. 17 Q. Okay. If you can scroll down, sir, to 18 Paragraph 123. Tell me when you are there. 19 A. Yes, I see that statement. 20 Q. Right. And it begins, "Dr. Panagos 21 describes TPPs as payors at risk for purchases of 22 affected valsartan containing drugs products." 23 A. Yes. 24 Q. And what are TPPs, as you refer to it 25 there?</p> <p>Page 251</p> <p>1 A. I think Dr. Panagos uses that abbreviation 2 for third-party payors. 3 Q. What is your understanding of a 4 third-party payor in this case? 5 A. It might be an insurance company or -- you 6 know, I'm trying to think of a term. You know, a 7 medical care organization that pays for medicinal 8 products. 9 Q. Uh-huh. Right. And then in the next 10 sentence you talk about risk about stopping your 11 antihypertensive treatment? 12 A. Yes. 13 Q. Right. You are talking about two 14 different types of risk here in this paragraph, 15 aren't you? 16 A. Well, I'm not sure I understand your 17 question. Perhaps you could continue. 18 Q. Sure. So in the first sentence you are 19 referring to TPPs as payors at risk, right? 20 A. Okay. 21 Q. Right. And then later you talk about, you 22 know, risks of stopping antihypertensive treatment, 23 right? 24 A. Yes. 25 Q. Right. So what I'm clarifying is: You</p>	<p>Page 252</p> <p>1 are not saying that TPPs were at any sort of 2 physical risk involving valsartan, right? 3 A. No, as I understand Dr. Panagos, she was 4 referring to financial risk. 5 Q. Right. I would agree with that. You 6 understand that TPPs are at financial risk for 7 purchases of their, say, insureds, right? 8 A. Yes. And now I see your point. It is two 9 different kinds of risks. 10 Q. Well, I appreciate your clarification. I 11 think we're on the same page. 12 And then in the next paragraph, in the 13 second sentence, you mention, "Both the TPPs and 14 patients got value for these products up to the 15 point they were recalled from the market." Do you 16 see that? 17 A. Yes. 18 Q. What do you mean by "value" there? 19 A. Well, I think it gets to my general 20 opinion that these were useful products. They were 21 pharmaceutical equivalent. They were bioequivalent. 22 They were AB-rated. And practitioners and patients 23 used them successfully for the indications such as 24 hypertension. 25 Q. Right. So are you opining on whether or</p> <p>Page 253</p> <p>1 not patients or TPPs received value for the 2 valsartan they purchased prior to the recalls? 3 A. I think if you look at my concluding 4 opinions, we have to pay attention to that. 5 Q. Of course. 6 A. My opinions are they were not adulterated. 7 They were pharmaceutically equivalent and 8 bioequivalent, and they were AB-rated. They were 9 not misbranded. 10 Q. Right. I'm -- 11 A. So I think I'm answering your question and 12 speaking specifically to my opinions. 13 Q. Right. I'm looking at your conclusions, 14 Doctor, at the very last page of your report, and I 15 don't see anything about opinions on who might have 16 received what value for valsartan products, so 17 that's what I'm trying to understand here. 18 A. I guess if I wanted to extend my 19 conclusions, my opinions to this particular 20 paragraph, I would say third-party payors got value. 21 Q. Uh-huh. And again, you define the value 22 that the third-party payors got as what? 23 A. In terms of getting a safe and effective 24 product that could be used to treat patients in 25 accordance with labeled indications.</p>
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<p style="text-align: right;">Page 254</p> <p>1 Q. And you are including in your definition 2 of a safe and effective drug products that have 3 nitrosamines in them, right? 4 A. Yes. And we know the products can have 5 nitrosamines in them. 6 Q. Including products that had nitrosamines 7 above the FDA's eventual limits, correct? 8 A. Well, that's the debatable point, and I'm 9 saying I just don't know if they had any different 10 safety and efficacy compared to the products below 11 that limit. 12 Q. Got it. You are not a -- you don't know 13 one way or the other whether a valsartan drug that 14 contains nitrosamines above the now-current FDA 15 limits had a different safety profile than valsartan 16 with nitrosamines below the now-current limits? 17 A. I think you are stating that correctly, 18 Mr. Stanoch. 19 Q. Uh-huh. Do patients have a choice when it 20 comes to the drugs that they are prescribed? 21 MS. LOCKARD: Objection. Speculation. 22 Outside the scope. 23 THE WITNESS: Well, they can certainly 24 talk to their doctors, and FDA encourages that, of 25 course. I would encourage it if I were at FDA. And</p>	<p style="text-align: right;">Page 256</p> <p>1 by, Doctor. 2 (Whereupon, Exhibit 14 was marked for 3 identification.) 4 BY MR. STANOCH: 5 Q. This is Exhibit 14. It should be Tab 32 6 in your binder. Tell me when you are there, sir. 7 A. Yes, I see this. Begins, "Expert: 8 Nitrosamines 'Can Slip Through.'" 9 Q. Correct. It's an article in Pharmacy 10 Times from June 29, 2021. Do you see that? 11 A. Yes, I do see it. 12 Q. And it says it includes a discussion with 13 "Edwin Gump, Ph.D., vice president of the Small 14 Modules Department at U.S. Pharmacopeia (USP)." Do 15 you see that? 16 A. Yes, I do see that. 17 Q. Are you familiar with Dr. Gump? 18 A. No, I'm not. 19 Q. Are you familiar with the Small Molecules 20 Department at USP? 21 A. Yes, I think I would -- I am familiar with 22 that. 23 Q. Uh-huh. And then if you want to -- if you 24 would flip to the third page of this document, sir. 25 Tell me when you are there.</p>
<p style="text-align: right;">Page 255</p> <p>1 I would say, yes, they do have a choice. 2 BY MR. STANOCH: 3 Q. But they would have no way of knowing, 4 would they, about whether the valsartan they 5 received prior to the recalls contained nitrosamines 6 or not, right? 7 A. Well, I'll make the general statement that 8 I don't think any label for a new drug approved by 9 the NDA or ANDA process has information about 10 impurities on the label. 11 Q. Uh-huh. So then based on the -- 12 valsartan's labeling part of the recalls, there is 13 no way a consumer would be able to make a decision 14 as to whether they wanted a valsartan product that 15 did or did not contain nitrosamines? 16 A. The only way they would know in this 17 particular instance is to read the FDA press 18 releases and talk to their physicians and 19 pharmacists. 20 Q. Right. And prior to those FDA press 21 releases, there was no way for them to know based on 22 the labeling alone? 23 A. Well, I think that's generally true, but 24 I'm not sure entirely. 25 Q. Okay. Let's mark another exhibit. Stand</p>	<p style="text-align: right;">Page 257</p> <p>1 MS. LOCKARD: You can -- to review it if 2 you need to. 3 THE WITNESS: Yeah, I'm looking at the 4 whole document just a second. It appears to be an 5 interview between a reporter, Alana, and Dr. Gump in 6 a publication for Pharmacy Times. So you want me to 7 go to the third page? One, two, three? 8 BY MR. STANOCH: 9 Q. Yes. Yep. 10 A. At the top it starts with, "class"? 11 Q. Yes, sir. If you could -- 12 A. Okay. Got it. 13 Q. Great. If you can go on that page down, 14 do you see the bolded name of the reporter, "Alana"; 15 you see that? 16 A. I do see that. 17 Q. Uh-huh. And she asks, "Right. Why are 18 nitrosamines of such particular concern?" You see 19 that? 20 A. Yes, yes. 21 Q. And why don't you read Dr. Gump's response 22 to that question, that first paragraph there, 23 beginning, "So"? 24 A. "So, I'm not a toxicologist, but 25 nitrosamines, from my reading, these are compounds</p>

<p style="text-align: right;">Page 258</p> <p>1 that have been studied for a number of years. 2 There's at least a number of compounds in this class 3 that are known mutagenic carcinogens. So, they're 4 basically fairly nasty cancer-causing actives." 5 Should I stop there? 6 Q. Yes. That's fine. I can ask questions on 7 that. 8 So do you agree with Dr. Gump that 9 nitrosamines are fairly nasty cancer-causing 10 actives? 11 MS. LOCKARD: Objection. Outside the 12 scope of his expert opinion in the 13 class-certification phase. You are asking him 14 causation opinions. 15 THE WITNESS: Well, I guess what I would 16 agree with is Dr. Gump says he is not a 17 toxicologist, and neither am I, so I agree with him 18 there. 19 BY MR. STANOCH: 20 Q. So would you agree with him that 21 nitrosamines are fairly nasty cancer-causing 22 actives? 23 MS. LOCKARD: Objection. Outside the 24 scope of his testimony. Asked and answered. 25 THE WITNESS: You know, I don't agree with</p>	<p style="text-align: right;">Page 260</p> <p>1 I mean, these are very general statements, but I 2 don't have a particular opinion about them, and they 3 don't relate to my report. 4 Q. Well, respectfully, sir, you are opining 5 on the value received from the drugs that are at 6 issue here. And I'm asking you, then, here if you 7 agree with Dr. Gump from the USP Small Molecule 8 Department about whether people don't really have a 9 choice when it comes to their drugs as opposed to 10 different foodstuffs and other things. 11 A. Is it -- 12 MS. LOCKARD: There is not a question 13 pending. 14 THE WITNESS: I just don't understand the 15 question. I mean, was there a question? Could you 16 rephrase it, perhaps, Mr. Stanoch? 17 BY MR. STANOCH: 18 Q. Do you agree that people can choose not to 19 eat their grilled burger, but people shouldn't have 20 to make a choice or have concerns about the quality 21 of their medicines? 22 MS. LOCKARD: Objection. Vague. Outside 23 the scope of his testimony for class certification. 24 THE WITNESS: And, you know, just 25 continuing on, you know, we can certainly</p>
<p style="text-align: right;">Page 259</p> <p>1 him there. That seems to be a fairly off-the-cuff 2 comment that would take a very sophisticated expert 3 to speak about the clinical impact of a particular 4 nitrosamine impurity. 5 BY MR. STANOCH: 6 Q. Uh-huh. Then would you agree with 7 Dr. Gump that nitrosamines are compounds that have 8 been studied for a number of years? 9 A. Yes, I think that's true. I would agree 10 with that. 11 Q. Uh-huh. Okay. Then why don't you move to 12 the last paragraph of that same page? It reads, 13 "But the one place." 14 A. "But the one place that people don't 15 really have a choice -- you can choose not to eat 16 that grilled burger -- but people shouldn't have to 17 make a choice" to "have concerns about the quality 18 of their medicines." 19 Q. Right. Do you agree with that statement 20 from Dr. Gump? 21 A. Well, again, these seem kind of very 22 general, unscientific statements. I mean, people 23 shouldn't have to make a -- can choose not to drink 24 your water that has nitrosamines. Does he want to 25 say that, that people should not drink their water?</p>	<p style="text-align: right;">Page 261</p> <p>1 cherry-pick statements out of this, but on the next 2 page it says, "The U.S. medicines supply is probably 3 the safest, or safe as any in the world, and we want 4 to make sure that the public really feels confident" 5 about "when they need to take a medicine that they 6 can do so and not have other things they have to 7 concern themselves about like nitrosamines." 8 I can certainly agree with that. 9 BY MR. STANOCH: 10 Q. You are agreeing to a different statement 11 that I didn't ask you about; is that what you just 12 did, Doctor? 13 A. Well, you are asking me to read at the 14 bottom of -- maybe I misread where you asked me to 15 read. If so, I apologize. 16 Q. Well, we have been at the same page, 17 Doctor. 18 A. Well, maybe I skipped over a page. Yes, 19 you had me read at the bottom of page 3; is that 20 correct, Mr. Stanoch? 21 Q. Yes, sir. 22 A. Yes, okay. I'm sorry. I jumped ahead. 23 Q. Again, do you agree with Dr. Gump's 24 statement in that paragraph, "But the one place that 25 people don't really have a choice -- you can choose</p>

<p>Page 262</p> <p>1 not to eat that grilled burger -- but people 2 shouldn't have to make a choice or have concerns 3 about the quality of their medicines"? 4 MS. LOCKARD: Objection. Vague. Outside 5 the scope of the expert witness report on class 6 certification. 7 THE WITNESS: If you are asking me if I 8 agree with Dr. Gump, I have to say I don't because, 9 you know, the presence of nitrosamine in food and 10 water and foodstuff is very uncertain, and it's 11 certainly not anything I talked about in my report. 12 But I'm not sure people can choose their foods and 13 their water so that they avoid nitrosamines. I just 14 don't know that. 15 Maybe he could make that point with regard 16 to a grilled burger, but what about all the other 17 grilled products and all the other foods that have 18 nitrosamines? It's a very general, if I may say, 19 uninformed statement, so that's why I am hesitating 20 to agree with it. 21 BY MR. STANOCH: 22 Q. So you don't agree? 23 A. I certainly agree that we need to control 24 nitrosamines in our medicines, and that's what this 25 entire effort, which began in 2018, is all about.</p> <p>Page 263</p> <p>1 Q. Are you aware of any efforts to control 2 nitrosamines in drug products prior to 2018? 3 A. I am not aware of that, Mr. Stanoch. 4 Q. Uh-huh. Would that be pertinent to the 5 opinions you are offering currently in this case? 6 A. I think it is generally in the sense that 7 science marches on, FDA marches on, drug regulation 8 gets better. We have many, many examples of that in 9 the United States. 10 And is it perfect? Are drugs perfect now? 11 No. But we can hope that in 10 or 20 years they 12 will be better than they are now. And what we see 13 happening here is an example of that happening with 14 regard to valsartan and nitrosamines. 15 Q. So you agree, then, that if information 16 was made known to a API manufacturer prior to the 17 2018 recalls about the potential for nitrosamine 18 impurities, that that should have been something 19 that was dealt with at that time, correct? 20 MS. LOCKARD: Objection. Vague. 21 THE WITNESS: I can't agree with it. It 22 does seem very vague. Perhaps you can restate the 23 question. 24 BY MR. STANOCH: 25 Q. Well, it sounds like you are saying nobody</p>	<p>Page 264</p> <p>1 knew about nitrosamines until the summer of 2018, 2 right? 3 A. That's what FDA says. I'm not saying 4 that. 5 Q. Uh-huh. Well, you are opining that 6 allegedly the FDA said it was unexpected and nobody 7 knew about it until summer of 2018, right? 8 A. Yes, FDA made a series of statements along 9 those lines. 10 Q. Right. 11 A. And it's definitely a part of my report. 12 Q. It certainly is. I can agree with that. 13 And then once the information came to 14 light about the nitrosamine impurities in valsartan, 15 the regulators in the industry took action, right? 16 A. Well, there was a series of events that 17 now have extended over the past four years and 18 extends to all the chemically synthesized drugs in 19 the country. So I guess you could say it's a very 20 comprehensive set of activities. 21 Q. And if that series of events -- oh, strike 22 that. 23 And if the information about nitrosamine 24 impurities in valsartan came to light earlier, that 25 series of events would have started earlier,</p> <p>Page 265</p> <p>1 correct? 2 MS. LOCKARD: Objection. Vague. 3 THE WITNESS: I suppose you could make 4 that hypothetical, and I wouldn't debate you. 5 BY MR. STANOCH: 6 Q. Let's flip to the fourth page of the 7 article in front of you, Doctor. 8 A. One, two, three, four. Okay. Is this the 9 page that starts at the top, "ones that" "need"? 10 Q. Correct, sir. If you can go down to the 11 paragraph where Mr. Gump's name is bolded again, and 12 it begins, "That's a great question." Do you see 13 that? 14 A. Yes, Dr. Gump, "That's a great question." 15 Q. Right. And then can you read the next 16 sentence? 17 A. "So, I think I mentioned that 18 manufacturers have a responsibility to evaluate 19 their processes and their products and look for 20 chance where they could have a risk of 21 nitrosamines." 22 Q. Do you agree with that statement? 23 A. Well, certainly, because Dr. Gump is 24 echoing the FDA guidance that came out well before 25 this interview --</p>
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1 Q. Uh-huh.
 2 A. -- particularly in February 2021, and this
 3 is the end of June 2021.
 4 Q. Uh-huh.
 5 A. Dr. Gump, if I may say so, is on very safe
 6 ground.
 7 Q. And would --
 8 (Reporter clarification.)
 9 THE WITNESS: Safe ground, S-A-F-E.
 10 BY MR. STANOCH:
 11 Q. Would you agree that prior to summer of
 12 2018 manufacturers had a responsibility to evaluate
 13 their processes and their products to look for the
 14 chances of genotoxic impurities?
 15 MS. LOCKARD: Objection. Outside the
 16 scope.
 17 THE WITNESS: Yes, I think that is what
 18 the guidance that we looked at before speaks to, and
 19 that had a date -- I guess it was a final date of
 20 2018.
 21 BY MR. STANOCH:
 22 Q. You are referring to the ICH guidance,
 23 correct?
 24 A. Yes, the M7.
 25 Q. Right. And then there were prior

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1 iterations of that same guidance, right?
 2 A. Yes. And other guidances, too, an ICH
 3 guidance and, I believe, an EMA guidance.
 4 Q. Uh-huh. And manufacturers would have
 5 responsibilities to evaluate their processes and
 6 products for genotoxic impurities under the prior
 7 iterations of the ICH and EMA guidance, whatever
 8 they may be at that period of time, right?
 9 A. Yes, and there are certainly other
 10 statements in Dr. Gump's interview that we could
 11 look to. But I'll wait for your questions,
 12 Mr. Stanoch.
 13 Q. Okay. Very good. So why don't we
 14 actually put that aside for now, Doctor.
 15 Some other questions about your
 16 professional experience, sir.
 17 A. Yes, please.
 18 Q. You are not a Pharm.D., correct?
 19 A. I am not.
 20 Q. Have you ever dispensed a drug?
 21 A. I have not.
 22 Q. Have you ever prescribed any valsartan or
 23 Diovan?
 24 A. I have not.
 25 Q. Have you prescribed any drug since 1990?

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1 A. You know, actually, I haven't. I don't
 2 write prescriptions.
 3 Q. Do you know what a pharmacy and
 4 therapeutics committee is?
 5 A. I do.
 6 Q. Okay. And what is that?
 7 A. Well, I would say it's a group of experts
 8 that build a formulary for a defined benefit offered
 9 to a community. So, for example, a hospital, a big
 10 hospital in an inner city may have a P&T committee
 11 that builds a formulary that the physicians and
 12 pharmacists in that community can use to write and
 13 dispense drugs -- write prescriptions and dispense
 14 drugs.
 15 Q. We can call that pharmacy and therapeutics
 16 committee a P&T committee, right?
 17 A. Yes, sir.
 18 Q. Have you ever served on a P&T committee?
 19 A. No.
 20 Q. Have you ever consulted with any P&T
 21 committee?
 22 A. Well, I remember during my days at USP I
 23 met with the Kaiser P&T committee to discuss how
 24 they work, but I wouldn't call that a consultation.
 25 Q. Okay. The --

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1 A. They weren't asking my opinion. It was
 2 more an exchange of information.
 3 Q. Fair enough. And roughly when was that?
 4 A. Oh, gee. 2010.
 5 Q. 2010. Have you ever been asked by any
 6 third-party payor to consult on their formulary
 7 designs?
 8 A. No. But I should mention perhaps at this
 9 point that USP was asked to consider model
 10 guidelines for formularies as part of the Medicare
 11 Part D benefit. And that was a large effort for the
 12 organization when I was there, and as far as I know,
 13 it's still continuing.
 14 Q. Were you part of that effort while you
 15 were working at USP?
 16 A. Yes, as a matter of fact, I chaired an
 17 expert committee which created the first model
 18 guidelines, and that was a very interesting effort.
 19 Q. Uh-huh. And what are the name of the
 20 guidelines?
 21 A. I would call them the USP model guidelines
 22 for the Part D -- to assess Part D formulary plans.
 23 Q. Uh-huh. You are not opining here, Doctor,
 24 about what information a P&T committee relies on
 25 when making decisions about reimbursements for drug

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1 products, correct?
 2 A. No, I am not.
 3 Q. All right. Have you ever worked for a
 4 third-party payor?
 5 A. I have not.
 6 Q. Do you know what a PBM is?
 7 A. It's a pharmacy benefit manager.
 8 Q. Have you ever worked for a PBM?
 9 A. No, I have not.
 10 Q. Have you ever consulted with a PBM
 11 professionally?
 12 A. No, I haven't.
 13 Q. Right. You are not here to opine on
 14 anything a PBM might rely on when it's making any
 15 determinations regarding a pharmacy benefit,
 16 correct?
 17 A. No. No. I don't believe that's any part
 18 of my opinions.
 19 Q. Okay. Let's mark another exhibit. Stand
 20 by.
 21 (Whereupon, Exhibit 15 was marked for
 22 identification.)
 23 BY MR. STANOCH:
 24 Q. This is Exhibit 15. It should be Tab 31
 25 in your binder, sir. Just let me know when you are

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1 there.
 2 A. I think it's coming toward me.
 3 Okay. I see something called ProPharma
 4 Group.
 5 Q. Right. And you can look through these
 6 pages, but this is all of the invoices that were
 7 produced to us for your work in this case. And if
 8 you can just look through them and confirm that this
 9 is the totality of the invoices for your work thus
 10 far in this case.
 11 A. ProPharma. I'm a little confused about
 12 ProPharma Group. Oh, maybe I shouldn't be confused
 13 about that group. Okay, yes, I see these are my
 14 invoices, and these invoices should be concurrent
 15 until the end of January of this year. Okay.
 16 Q. Right. I mean, the first few pages, I see
 17 the ProPharma Group, dated 11/30/21. Do you see
 18 that?
 19 A. 11/30/2021, yes, I do see that.
 20 Q. Right. And then the next few pages is for
 21 work from an invoice dated 12/31/21, right?
 22 A. Yes, I submit my hours monthly.
 23 Q. And then the next page after that is an
 24 invoice for your work through January 31, 2022,
 25 right?

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1 A. Well, wait a minute. I see a third page
 2 that looked like July 2021. Yes, that could be
 3 true.
 4 Q. Right. Well, I guess there is a couple
 5 things here. First is: Why do some of your
 6 invoices say ProPharma Group and the other one at
 7 the end says NDA Partners?
 8 A. My consulting group, NDA Partners, was
 9 sold in 2021 to a larger company called Planet
 10 Pharma, and then Planet Pharma in turn merged with
 11 ProPharma, so the overarching organization for my
 12 consulting group, which still exists as NDA
 13 Partners, is ProPharma Group.
 14 Q. Got it.
 15 A. And they do the billing.
 16 Q. Did anyone at NDA Partners or ProPharma
 17 Group assist you in the preparation of your report
 18 that you submitted in this case?
 19 A. No, not at all.
 20 Q. Okay. You and you alone wrote your
 21 report?
 22 A. Yes, I think that's quite true. I wrote
 23 this report.
 24 Q. And the invoice at the end that is on the
 25 NDA Partners letterhead, it's dated 7/31/2021?

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1 A. Yeah, I think we may be looking at the
 2 transition from NDA Partners to ProPharma --
 3 Q. Uh-huh.
 4 A. -- so that's an interesting observation.
 5 Q. And it looks like your first billed work
 6 in this matter was 7/1/2021, right?
 7 A. That's when I was first contacted by
 8 counsel, and then there was a hiatus. I really
 9 didn't begin substantive work on this report until
 10 November. You can see that in the invoices.
 11 And the reason I didn't do any detailed
 12 work in July until November was because I was not
 13 involved in the causation discussions.
 14 Q. Then if you look on the ProPharma Group
 15 invoice dated 1/31/2022, the first entry is for work
 16 on January 3rd, 2022, correct?
 17 A. Wait a minute. I'm having trouble
 18 catching up with you. But I'm setting aside the
 19 July one. Now there is one -- I see a July invoice.
 20 If that's what you are talking about, yes, I see
 21 that invoice.
 22 Q. And just to go through this, a few things.
 23 You say, "Review 82 documents in triplicate." Do
 24 you see that?
 25 A. Yes, I do.

<p style="text-align: right;">Page 274</p> <p>1 Q. What do you mean by "in triplicate"?</p> <p>2 A. Well, I'm laughing a little bit because I</p> <p>3 think I got the same folder three times. I had to</p> <p>4 check with counsel many times to make sure that they</p> <p>5 were the same documents in the three folders. So</p> <p>6 that's what that was all about, and I did have a</p> <p>7 good review with counsel about the materials I</p> <p>8 received and where it was all filed.</p> <p>9 Q. Uh-huh. And then further down here, you</p> <p>10 have some entries for, "Read DB deposition," "Read</p> <p>11 EG deposition"; do you see those?</p> <p>12 A. Yes, those refer -- for example, "EG"</p> <p>13 refers to Elizabeth Gray. The "DB" refers, I</p> <p>14 believe, to Daniel Barreto.</p> <p>15 Q. Uh-huh.</p> <p>16 A. And then you can see Panagos expert</p> <p>17 reports.</p> <p>18 Q. Uh-huh. And then that last entry, should</p> <p>19 that be DB deposition as well?</p> <p>20 A. Well, I'm not sure about that. No, I</p> <p>21 think it may be a Binsol deposition.</p> <p>22 Q. Uh-huh. So sometimes you listed the</p> <p>23 specific deposition you read, and sometimes you</p> <p>24 didn't, it looks like; is that right?</p> <p>25 A. I could agree that the way I fill out my</p>	<p style="text-align: right;">Page 276</p> <p>1 A. How can I assist?</p> <p>2 Q. When you say, "Write CBE-30," are you</p> <p>3 referring to sections of your report?</p> <p>4 A. Yes.</p> <p>5 Q. Okay. You weren't writing a CBE-30</p> <p>6 separately outside of your work, right?</p> <p>7 A. Not at all. Oh, no, no, that would not be</p> <p>8 true.</p> <p>9 Q. Uh-huh. And when you say, "Attempt to</p> <p>10 review ANDA files," what does that mean?</p> <p>11 A. Well, ANDA, as you know, the ANDA files</p> <p>12 were very broad and deep and complex. So I would</p> <p>13 say I could review them from a high level, but I</p> <p>14 would not claim that -- I certainly wouldn't claim</p> <p>15 to counsel that I was reviewing the ANDAs in detail.</p> <p>16 Q. Got it. And it looks that throughout all</p> <p>17 of your invoice work, your rate was the same, the</p> <p>18 \$695 an hour?</p> <p>19 A. Yes. And remember, that is what goes to</p> <p>20 the company. That's not what comes to me.</p> <p>21 Q. Uh-huh. What portion do you get?</p> <p>22 A. It's 80 percent.</p> <p>23 Q. Okay. And you don't need a calculator,</p> <p>24 Doctor, unless you want it, but ballpark it looks</p> <p>25 like the invoices for your work to date for this</p>
<p style="text-align: right;">Page 275</p> <p>1 hours might not be entirely consistent.</p> <p>2 Q. And I'm not going to take issue with that,</p> <p>3 Doctor. I just want to make sure, though, that even</p> <p>4 if you call out specific deposition transcripts here</p> <p>5 in your invoices, is it your position that you did</p> <p>6 review all the deposition transcripts that were in</p> <p>7 your materials considered?</p> <p>8 A. No, I didn't look at all the depositions.</p> <p>9 I selected certain depositions that seemed</p> <p>10 particularly important.</p> <p>11 Q. Which ones, then, did you review?</p> <p>12 A. Well, we can see from this, I would say</p> <p>13 Daniel Barreto, Elizabeth Gray and Mr. Binsol.</p> <p>14 There may have been others, but I might have left</p> <p>15 them out of my invoice.</p> <p>16 Q. Uh-huh. And if you flip back to the -- I</p> <p>17 guess the second page.</p> <p>18 A. I'm trying to stay with you on page</p> <p>19 numbers.</p> <p>20 Q. Well, I guess it -- yeah, I guess it would</p> <p>21 be page 1 of 2.</p> <p>22 A. Is this December?</p> <p>23 Q. Yes. December 31, 2021.</p> <p>24 A. Yes, I'm looking at all that.</p> <p>25 Q. Uh-huh.</p>	<p style="text-align: right;">Page 277</p> <p>1 matter is approximately \$90,000 or so?</p> <p>2 A. Yes. Let's say 80 percent of that would</p> <p>3 come to me, if we're calculating it that way.</p> <p>4 Q. Understood. All right. You can put those</p> <p>5 aside for now. Thank you.</p> <p>6 Can you pull up your -- I guess it would</p> <p>7 be Exhibit A to your report, sir. I'm looking at</p> <p>8 page 28 of 29 of Exhibit A. It's your prior</p> <p>9 deposition testimony.</p> <p>10 A. Yes, I think it's coming to me. Just a</p> <p>11 second.</p> <p>12 Q. Sure. Let me know when you are there.</p> <p>13 A. Wait a minute. I have it in my CV here.</p> <p>14 (Whereupon, a brief discussion off the</p> <p>15 record.)</p> <p>16 THE WITNESS: I should have it in front of</p> <p>17 me. Hold on just a sec.</p> <p>18 MS. LOCKARD: Here you go.</p> <p>19 THE WITNESS: Oh.</p> <p>20 Okay. I'm with you, Mr. Stanoch. Please</p> <p>21 proceed.</p> <p>22 BY MR. STANOCH:</p> <p>23 Q. Great. And here you have listed, it looks</p> <p>24 like, 14 matters in the last four years, right?</p> <p>25 A. I'm counting 20, with the most recent</p>

<p style="text-align: right;">Page 278</p> <p>1 being the trial testimony in November 17th. Are you 2 cutting off some because they are not in the last 3 four years? 4 Q. Oh, no, I'm sorry. The one I'm looking 5 at -- maybe I have an older version in front of 6 me -- only had 14 numbered entries. Let me look at 7 something else. 8 A. It got cut off, but I see 20 in my CV in 9 the final pages. But you may be right if we are 10 just counting the last four years. 11 Q. Well, how many numbered matters do you 12 have in the version that you are looking at, Doctor, 13 20? 14 A. I have 20, yes. 15 Q. Okay. And starting from the top of that, 16 could you -- I just want to know what party you were 17 retained by and in whose behalf you were offering 18 opinions. 19 A. Oh, the first one I actually can't 20 remember. I'd have to look it up to tell you. 21 The second one was sort of a -- it was 22 a -- I could say it this way. It was a squabble 23 between a lot of people. It really didn't have 24 much -- it didn't have anything to do with FDA, 25 really. And it was an individual where some people</p>	<p style="text-align: right;">Page 280</p> <p>1 Restasis was antitrust. 2 Biogen was -- versus Acorda was related to 3 an FDA guidance where I offered testimony. 4 Stewart, Sandoz was failure to warn. 5 Glumetza was antitrust, and that's still 6 active. 7 Braeburn versus Camurus, that was a 8 company squabble where I was on the side of 9 Braeburn. 10 And then Ranbaxy is still -- I'm sorry. 11 The Glumetza, I think, settled, and the Ranbaxy is 12 still in progress, but it's antitrust. I'm on the 13 side of the plaintiffs. 14 Genentech versus InterMune was patent. I 15 was on the side of InterMune, the pioneer. 16 Mallinckrodt versus debtors, that was a 17 squabble between third-party payors, if you will, 18 and Mallinckrodt, and I was on the Mallinckrodt 19 side. 20 Is that helpful, Mr. Stanoch? 21 Q. No, it is. I appreciate you going through 22 that. 23 And, Doctor, for the prior cases you have 24 offered expert opinions in, for those that are class 25 actions, is it fair to say you have always been</p>
<p style="text-align: right;">Page 279</p> <p>1 were complaining that he had taken intellectual 2 property from a firm. 3 Supernus versus Actavis I think was a 4 patent issue, and I was on the Supernus side. 5 The fourth one I think was antitrust. 6 The fifth one was a debate about a generic 7 company versus Shire, and I was on the Shire side. 8 Solodyn was antitrust. I was on the part 9 of plaintiffs. 10 Loestrin I think was antitrust, and that 11 was on the part of plaintiffs. 12 Arbor versus ANI was sort of a company 13 squabble, and I was on the ANI side. 14 Fresenius Kabi and Par was an argument 15 about -- I'm summarizing very briefly, but I think 16 it was restraint of trade, and I was on the Par 17 side. They were the defendants, as I recall. 18 Galderma versus Teva was patent, and I was 19 on the Teva side as the -- I'm struggling with what 20 they were. Yeah, they got sued, so they were the 21 defendant. 22 Belcher versus Hospira. I don't remember 23 that one. I'd have to look it up. I apologize. 24 Continuing, Vision versus Sunrise, that 25 was a sort of company squabble over GMPs.</p>	<p style="text-align: right;">Page 281</p> <p>1 retained by a defendant in those actions? 2 A. You know, I'm not sure that I would 3 identify any of those as class actions. I have to 4 say I'm a little uncertain about just what a class 5 action is, and so I couldn't say I was on one side 6 or the other. 7 If you say an antitrust is a class action, 8 I think I would agree with you that I'm usually on 9 the side of plaintiffs, but I have one now where I 10 believe it's antitrust and I'm on the side of the 11 pioneer -- 12 Q. But you just said -- 13 A. -- so I don't think I can agree with you 14 that I'm always on one side versus another. 15 Q. Uh-huh. But you are on the side of the 16 defendants now in this case, right? 17 A. Yes. 18 Q. All right. And, the extent you remember, 19 just go through and tell me where you think you were 20 on the side of the defendants in your list of cases. 21 A. Oh, dear. Well, I'll give some examples. 22 I think Mallinckrodt was the defendant. They were 23 getting -- in Genentech I was on the side of the 24 plaintiff. 25 Ranbaxy, I was on the side of plaintiff.</p>

<p style="text-align: right;">Page 282</p> <p>1 Braeburn, I think they were the 2 defendants. 3 At Stewart, I was on the side of Sandoz. 4 That was the defendants. 5 Can't remember Biogen. 6 Restasis I was on the side of the payors, 7 so they would be the plaintiffs. 8 I better stop there because I'm a little 9 uncertain about my answers. 10 Q. Okay. If you are uncertain, that's okay, 11 Doctor. I don't need you to guess. That's quite 12 all right. 13 Stand by. 14 MS. LOCKARD: We have been going over an 15 hour, so if you get to a good breaking point, that 16 would be helpful. 17 BY MR. STANOCH: 18 Q. All right. Doctor, I just want -- 19 MR. STANOCH: Yeah, we'll take a break 20 soon, Counsel. 21 Q. Doctor, I just want to go back to your -- 22 oh, what was it, Tab -- I think it was Exhibit 2. 23 It was Exhibit 2, sir. It was the Roger Williams 24 list of materials considered, 2/17/2022. 25 A. Yes, I have that before me, Mr. Stanoch.</p>	<p style="text-align: right;">Page 284</p> <p>1 A. No. 2 Q. Okay. All right. I'm going to mark, 3 Doctor, a copy of the CV and your prior testimony in 4 cases which was provided to me by Teva's counsel 5 during the break that will be marked as Exhibit 16. 6 (Whereupon, Exhibit 16 was marked for 7 identification.) 8 MR. STANOCH: So that should be available 9 to everyone. 10 I will also mark at this time, as 11 Exhibit 17, the video webinar from which the USP 12 excerpt stills were taken. 13 (Whereupon, Exhibit 17 was marked for 14 identification.) 15 MR. STANOCH: And I have no further 16 questions at this time. I'll reserve my time 17 pending counsel's questions. Thank you, 18 Dr. Williams. 19 THE WITNESS: Thank you, Mr. Stanoch. 20 (Whereupon, a brief discussion off the 21 record.) 22 EXAMINATION 23 BY MS. LOCKARD: 24 Q. Okay. Dr. Williams, a copy of your CV was 25 just marked as Exhibit No. 16.</p>
<p style="text-align: right;">Page 283</p> <p>1 Q. And I want to make sure I understood this. 2 So the materials listed here, you may or may not 3 have looked at some of these things, but you are 4 only relying on them for purposes of your report if 5 they are cited in the body or footnotes of your 6 report, right? 7 A. Yes, I think that's a fair summary. 8 Q. Fine. 9 MR. STANOCH: Let's take a break, then. 10 THE VIDEOGRAPHER: Okay. We are going off 11 the record. The time is 3:00 p.m. 12 (Whereupon, a brief recess was taken.) 13 THE VIDEOGRAPHER: Okay. We are coming 14 back on the record. The time on the video monitor 15 is 3:35. Please begin. 16 BY MR. STANOCH: 17 Q. Okay. Welcome back, Doctor. During that 18 lengthy break, did you talk to anyone besides your 19 counsel? 20 A. No, not at all. 21 Q. Did you communicate with anyone besides 22 the counsel in the room with you about your 23 testimony? 24 A. No, not at all. 25 Q. Did you review any documents?</p>	<p style="text-align: right;">Page 285</p> <p>1 Do you have a copy of that in front of 2 you? 3 (Whereupon, a brief discussion off the 4 record.) 5 THE WITNESS: Yes, I do. 6 BY MS. LOCKARD: 7 Q. All right. For the benefit of the jury 8 and counsel, can you please give us the benefit of 9 your educational background? 10 MR. STANOCH: Objection to form. Beyond 11 the scope. 12 BY MS. LOCKARD: 13 Q. You can continue. 14 A. My undergraduate degree was a premed 15 degree, and then after I completed my undergraduate 16 studies, I went to medical school at the University 17 of Chicago. I stayed on after my medical degree and 18 obtained an internship and residency in internal 19 medicine at the University of Chicago. And I 20 received honors, both in undergraduate, Phi Beta 21 Kappa, as well as medical school, called AOA, which 22 is the equivalent of Phi Beta Kappa. 23 Then I entered the U.S. Army, and that was 24 a deferred draft, where I stayed for three years. I 25 actually did research on malaria at Walter Reed</p>

<p style="text-align: right;">Page 286</p> <p>1 during the latter half of my service. In the first 2 half I was stationed in Seoul, Korea. 3 When I finished that service, I entered a 4 clinical pharmacology fellowship at the University 5 of California, San Francisco. That lasted three 6 years. And based on my training, I was able to 7 obtain Board certification in both internal medicine 8 and clinical pharmacology. 9 Q. Were you an officer in the Army? 10 A. Yes, I was a major. 11 Q. What licenses have you held? 12 A. I was licensed to practice medicine in 13 California, but I didn't continue that or my Board 14 certifications when I came to FDA in 1990 because it 15 was a full-time job at FDA and I was not practicing 16 clinical medicine. 17 Q. Have you held any licenses in 18 pharmacology? 19 A. Clinical pharmacology. There is no 20 licensure, but I was Board-certified in clinical 21 pharmacology. 22 Q. What did you do when you left private 23 practice or -- as a medical doctor? 24 MR. STANOCH: Objection to form. 25 Go ahead.</p>	<p style="text-align: right;">Page 288</p> <p>1 the level of the center, where I held multiple 2 positions, but I ended my career and the last 3 several years of my time at FDA working as a deputy 4 director for the center director, who was Dr. Janet 5 Woodcock at the time. Dr. Woodcock is now the 6 commissioner of FDA on an acting basis. 7 And in my role as deputy center director, 8 I had a lot of responsibilities, but I was 9 principally the director of the Office of 10 Pharmaceutical Science. That office is now the 11 Office of Pharmaceutical Quality at FDA. And I had 12 oversight for the Office of Generic Drugs, the 13 Office of Clinical Pharmacology and Biopharmaceutics 14 and the Office of Testing and Research and also the 15 Office of Chemistry. So I had a terrific experience 16 overseeing about four or five of the disciplines 17 that contribute to the review of an NDA, as well as 18 oversight for the Office of Generic Drugs and many 19 other responsibilities. 20 I then left FDA in 2000. I became chief 21 executive officer and chair of the Council of 22 Experts. And I would say over my 14-year period 23 there was a rapid expansion of USP, a globalization 24 of our activities, a focus on the science of 25 metrology, which I think is the undergirding science</p>
<p style="text-align: right;">Page 287</p> <p>1 THE WITNESS: I would say I was never in 2 private practice. I worked at the University of 3 California, San Francisco, doing clinical 4 investigations for NDA and ANDA sponsors. And it 5 was there that I built a focus on bioavailability 6 and bioequivalence that I think has continued 7 throughout my career. 8 I spent a year after my service at UCSF in 9 a small company in South San Francisco that was 10 studying an HIV medicine. 11 And then Dr. Carl Peck, who has been a 12 very good mentor and friend, brought me to FDA in 13 1990 to head up the Office of Generic Drugs. And 14 for those who may remember, that was a difficult 15 time for both the generic industry and FDA. It had 16 to do with something that briefly is called the 17 generic drug scandal. 18 But I was very pleased to work in the 19 Office of Generic Drugs. We worked with Congress 20 and with industry to sort of straighten it all out. 21 And I think we did get it straightened out. We sort 22 of put it back on a solid footing. And the office 23 has zoomed, if you will, ever since then over the 24 ensuing decades. 25 In 1993, Dr. Peck left, so I came up to</p>	<p style="text-align: right;">Page 289</p> <p>1 for what USP does, and the addition of a lot of 2 compendia. 3 USP started out, when I was there, with 4 USP-NF. Those are official compendia of the United 5 States. But we added Food Chemical Codex, a Dietary 6 Supplement Compendium. We even experimented with a 7 novel compendium that we called the Medicines 8 Compendium. 9 And overall it was a very remarkable 10 experience, and I am forever grateful for having 11 that experience. 12 Q. What -- 13 A. After leaving USP, I became a consultant 14 at the invitation of Dr. Peck again. Dr. Peck has 15 been a great mentor, and he was the center director 16 who brought me to FDA. And I have continued doing 17 consulting in his consulting group, called NDA 18 Partners, as we have discussed, and over the last 19 several years I've focused primarily on litigation. 20 Q. How many years were you at the FDA, 21 Dr. Williams? 22 MR. STANOCH: Objection to the form. 23 THE WITNESS: Ten. 24 BY MS. LOCKARD: 25 Q. How many years were you at the United</p>

<p>Page 290</p> <p>1 States Pharmacopeial Convention, the USP?</p> <p>2 A. Fourteen.</p> <p>3 MR. STANOCH: Same objection.</p> <p>4 BY MS. LOCKARD:</p> <p>5 Q. What year did you leave the USP?</p> <p>6 A. It was the beginning of 2014.</p> <p>7 Q. And your CV that was marked as Exhibit 16,</p> <p>8 I was following along, but it has the dates and</p> <p>9 specific responsibilities and titles for your</p> <p>10 positions at FDA, USP and otherwise. Is that still</p> <p>11 accurate?</p> <p>12 A. Yes, no changes.</p> <p>13 Q. There are a number of honors and awards</p> <p>14 listed here in your CV. Are those still active?</p> <p>15 MR. STANOCH: Objection.</p> <p>16 THE WITNESS: Yes, no changes.</p> <p>17 (Reporter clarification.)</p> <p>18 THE WITNESS: No changes in those honors</p> <p>19 and awards.</p> <p>20 BY MS. LOCKARD:</p> <p>21 Q. Have there been any changes in your board</p> <p>22 memberships or research awards listed on your CV?</p> <p>23 A. No, none. And I would say in my quasi</p> <p>24 retirement that's all been -- it's been replaced, if</p> <p>25 you will, by the litigation efforts.</p> <p>Page 291</p> <p>1 Q. Have you done any teaching work?</p> <p>2 MR. STANOCH: Objection.</p> <p>3 THE WITNESS: Yes, I would say at UCSF I</p> <p>4 taught pharmacy and medical students and also worked</p> <p>5 with graduate students on their Ph.D.s.</p> <p>6 BY MS. LOCKARD:</p> <p>7 Q. Have you served on any editorial boards?</p> <p>8 MR. STANOCH: Objection.</p> <p>9 THE WITNESS: I have been a reviewer for</p> <p>10 multiple journals and --</p> <p>11 BY MS. LOCKARD:</p> <p>12 Q. Any that would be relevant to this</p> <p>13 litigation?</p> <p>14 MR. STANOCH: Uh-huh. A standing</p> <p>15 objection to background.</p> <p>16 Go ahead.</p> <p>17 THE WITNESS: Well, yes, I think all of my</p> <p>18 writings and research in one way or another relate</p> <p>19 to what we're talking about here in this, the</p> <p>20 quality of medicines, therapeutic equivalence,</p> <p>21 substitution, metrology, measurements. I feel</p> <p>22 everything in my wheelhouse, if you will, is related</p> <p>23 to this litigation.</p> <p>24 BY MS. LOCKARD:</p> <p>25 Q. Do you have any estimates in terms of how</p>	<p>Page 292</p> <p>1 many journal articles you have contributed to?</p> <p>2 A. Well, if you add all my publications,</p> <p>3 including the USP publications, I think we're well</p> <p>4 over 200.</p> <p>5 Q. Have you participated in writing any books</p> <p>6 or book chapters?</p> <p>7 A. Yes, I have done that.</p> <p>8 Q. How many of those?</p> <p>9 A. I think you would have to look at the CV,</p> <p>10 but I'm sure we're in the scores, maybe, or between</p> <p>11 10 and 20.</p> <p>12 Q. And are those journal articles and book</p> <p>13 chapters all listed on your CV, Dr. Williams?</p> <p>14 A. Yes, I think the CV is complete.</p> <p>15 Q. Oh, I would like to attach as Exhibit 18 a</p> <p>16 complete copy of your set of materials that we sent</p> <p>17 for your consideration. And we have been handed a</p> <p>18 thumb drive of that which we can get to the court</p> <p>19 reporter.</p> <p>20 (Whereupon, Exhibit 18 was marked for</p> <p>21 identification.)</p> <p>22 MS. LOCKARD: Exhibit 18, for the record,</p> <p>23 is going to be Dr. Williams' file.</p> <p>24 MR. STANOCH: Counsel, this is everything</p> <p>25 listed in the -- what do you call it, the materials</p> <p>Page 293</p> <p>1 considered, Exhibit 2?</p> <p>2 MS. LOCKARD: That's correct.</p> <p>3 MR. HARKINS: Yes, yeah.</p> <p>4 MS. LOCKARD: Yes.</p> <p>5 MR. STANOCH: Okay.</p> <p>6 MR. HARKINS: Also including the copy of</p> <p>7 the revised list of materials considered that was</p> <p>8 submitted with the production of those materials two</p> <p>9 days ago.</p> <p>10 (Whereupon, a brief discussion off the</p> <p>11 record.)</p> <p>12 BY MS. LOCKARD:</p> <p>13 Q. All right. Dr. Williams, you were asked</p> <p>14 about a document we reviewed earlier today on a</p> <p>15 break that was identified as Exhibit 3, and it was</p> <p>16 the GNTM e-mail. Do you recall being asked about</p> <p>17 that?</p> <p>18 A. I do recall.</p> <p>19 Q. And did that document refresh your</p> <p>20 recollection about how Teva learned of the</p> <p>21 nitrosamine issue initially?</p> <p>22 MR. STANOCH: Objection to form.</p> <p>23 THE WITNESS: Yes.</p> <p>24 MR. STANOCH: Asked and answered.</p> <p>25 Go ahead.</p>
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<p style="text-align: right;">Page 294</p> <p>1 THE WITNESS: Yes. This is definitely a 2 document I cited. It was very important to my 3 opinions. 4 And it has a huge distribution list, GNTM, 5 global notice to management, where Teva is 6 communicating to its scores of sites across the 7 globe. 8 And it starts -- it's an incident 9 category, foreign matter, and it says, "On 10 June 20th, 2018, vendor" ZHP "notified Teva that 11 they came to be aware of a previously unknown 12 impurity that may have genotoxic potential." 13 BY MS. LOCKARD: 14 Q. But let me stop you there and ask: So 15 does that clarify for you how Teva learned of the 16 potential -- 17 A. Yes. 18 Q. -- impurity? 19 A. Yes. 20 MR. STANOCH: Objection. 21 THE WITNESS: And then it -- 22 BY MS. LOCKARD: 23 Q. Okay. And the next question is: On that 24 date of the initial notification, is there anything 25 there that indicates what the potential impurity</p>	<p style="text-align: right;">Page 296</p> <p>1 THE WITNESS: No, I would say it is not. 2 BY MS. LOCKARD: 3 Q. You were asked some questions about 4 Novartis and testing they allegedly did on some of 5 their products. Do you recall that? 6 A. I do. 7 Q. Do you have any information about 8 Novartis' testing of their Diovan or any other 9 products with respect to nitrosamines? 10 A. No, I don't recall seeing any information, 11 and it was not pertinent to my report. 12 Q. Do you know why Novartis was testing or 13 what they were testing, if at all? 14 A. No, I really don't. I have no information 15 about it that I remember. 16 Q. -- Novartis testing relevant to any of the 17 opinions you have given to date in this case? 18 MR. STANOCH: Objection. 19 THE WITNESS: It is not. 20 BY MS. LOCKARD: 21 Q. You were asked some questions about the 22 limits of the nitrosamine, either interim limits or 23 permanent limits, by FDA. Are you offering any 24 opinions about whether those limits were 25 appropriate?</p>
<p style="text-align: right;">Page 295</p> <p>1 was? 2 A. I don't see that here. I may be missing 3 it, but I don't see that it states the impurity. 4 Q. You can put that aside for the moment. 5 Are 483s a final agency determination? 6 A. No. I would say they are a set of 7 observations from an Office of Regulatory inspector, 8 typically, who is visiting a manufacturing site and 9 writing observations over a several-day period, 10 either in the United States or overseas. 11 Q. Are warning letters a final agency 12 determination? 13 A. The way I would say it is the warning 14 letter is an escalation of FDA's concern. I 15 sometimes say it's kind of a shot across the bow of 16 a company, that they better pay closer attention to 17 what FDA is saying and do something. 18 But even there, the company is allowed to 19 respond, allowed to resolve issues and ultimately 20 allowed to have their manufacturing site cleared of 21 the issues and the inspection closed out by FDA 22 satisfactorily. 23 Q. So then is a warning letter necessarily a 24 final determination by FDA? 25 MR. STANOCH: Objection to form.</p>	<p style="text-align: right;">Page 297</p> <p>1 A. No, I am not. 2 Q. Have you endeavored to render any opinions 3 about the testing methodology employed to detect 4 limits of nitrosamines? 5 A. No, it's not part of my opinion, although 6 I mention it in my report. 7 Q. Do you have any opinions in this case 8 about whether nitrosamines are or are not 9 carcinogenic? 10 MR. STANOCH: Objection to form. 11 THE WITNESS: No, I'm not offering any 12 opinion that speaks to pharmacology/toxicology of 13 the nitrosamines. 14 BY MS. LOCKARD: 15 Q. Do you intend to offer any opinions about 16 whether nitrosamines in the Teva products were a 17 potential human carcinogen? 18 MR. STANOCH: Objection to form. 19 THE WITNESS: No, I don't offer that 20 either. 21 BY MS. LOCKARD: 22 Q. Counsel made the point earlier today that 23 even if the USP does not provide for testing of 24 nitrosamines, that a manufacturer can still 25 institute its own testing for nitrosamine.</p>

<p style="text-align: right;">Page 298</p> <p>1 MR. STANOCH: Objection. There's no 2 question. 3 THE WITNESS: That's absolutely true. A 4 manufacturer can build additional testing into its 5 private specification working with FDA. 6 BY MS. LOCKARD: 7 Q. Well, in order for a company to initiate 8 testing of a genotoxic impurity, what do they need 9 to know? 10 A. Well, that relates to something FDA said 11 in some of their public announcements. You have to 12 suspect that it's there. You wouldn't test for it 13 if you didn't think it was there, so you first have 14 to have a suspicion that it's there. And then I 15 would say you would have to see some identifiable 16 peak on a chromatogram that raises your concern, and 17 that would lead into an understanding of looking at 18 the impurity and assessing its genotoxic potential. 19 Q. Did you in this case endeavor to do an 20 independent assessment, at this stage of the case, 21 whether Teva violated any cGMPs? 22 MR. STANOCH: Objection to form. 23 THE WITNESS: The only thing I did was 24 look at FDA's record of inspections of Teva's GMPs 25 at its Malta and Jerusalem sites, but I didn't do</p>	<p style="text-align: right;">Page 300</p> <p>1 BY MS. LOCKARD: 2 Q. Do you understand that at some point we 3 may ask you to review additional materials and 4 render liability opinions? 5 A. Yes, I understand that may come later on, 6 but it is not happening now. 7 Q. Are you willing to do that if so asked? 8 A. Yes. 9 Q. Are you qualified to do so at certain 10 elements if so asked? 11 MR. STANOCH: Objection. Form. 12 THE WITNESS: I believe so. 13 BY MS. LOCKARD: 14 Q. You were asked some questions about what 15 do plaintiffs or patients expect; do you remember 16 that? 17 A. I do remember that. 18 Q. Do you intend to offer any opinions about 19 plaintiffs' expectations in this case? 20 MR. STANOCH: Objection to form. 21 THE WITNESS: No, I mean, I tried to 22 answer those questions as best I could, but they 23 were not part of my report and not part of my 24 opinions. 25</p>
<p style="text-align: right;">Page 299</p> <p>1 any independent evaluation of Teva's GMP adherence. 2 BY MS. LOCKARD: 3 Q. Have you endeavored to do any independent 4 assessment of Teva's compliance with any of its 5 policies or procedures? 6 A. No, not at all. That was not part of my 7 report, and then I didn't cite to any documents to 8 that point. 9 Q. Now, you were asked about the purpose of 10 your report, and you have heard a lot of objections 11 today about the class-certification opinions that 12 you rendered in your report. Do you have an 13 understanding that you have not been asked by me or 14 my firm to provide any liability opinions at this 15 point in time? 16 MR. STANOCH: Objection to form. 17 THE WITNESS: I do understand that. 18 BY MS. LOCKARD: 19 Q. Have you intended to give liability 20 opinions today? 21 A. No. 22 MR. STANOCH: Objection. Form. 23 THE WITNESS: I have tried not to give 24 liability opinions. 25</p>	<p style="text-align: right;">Page 301</p> <p>1 BY MS. LOCKARD: 2 Q. Do you intend to offer any opinions about 3 various choices available to plaintiffs who were 4 prescribed hypertension medications; is that what -- 5 MR. STANOCH: Objection to form. 6 BY MS. LOCKARD: 7 Q. -- hired to do? 8 MR. STANOCH: Sorry. Sorry, Counsel. 9 Objection to form. 10 THE WITNESS: No, I -- 11 (Reporter clarification.) 12 MR. STANOCH: I apologize. I was just 13 objecting. I'm sorry, Victoria. 14 THE REPORTER: Okay. So sorry. 15 BY MS. LOCKARD: 16 Q. I think I said, is that what you were 17 hired to do? 18 A. No. 19 Q. And recognizing you have a medical degree, 20 but do you prescribe, consult, discuss with patients 21 hypertension medications? 22 A. No, not at all. I am not a practicing 23 clinical doctor. 24 Q. You were also asked to discuss some issues 25 with respect to recycled solvents in the API that</p>

<p style="text-align: right;">Page 302</p> <p>1 Teva was supplied. Do you recall that?</p> <p>2 A. I do.</p> <p>3 Q. And are you familiar with recycled</p> <p>4 solvents being used in pharmaceutical manufacturing?</p> <p>5 A. You know, actually I'm not. The first</p> <p>6 time I read about it was when I started reading</p> <p>7 materials for this report.</p> <p>8 Q. Is it something that you would ordinarily</p> <p>9 be involved in, in terms of your role at USP or FDA,</p> <p>10 to investigate recycled solvents?</p> <p>11 MR. STANOCH: Objection to form.</p> <p>12 THE WITNESS: No. No, really not. To me</p> <p>13 it seems more like a GMP issue, and I don't speak as</p> <p>14 a GMP expert.</p> <p>15 (Whereupon, a brief discussion off the</p> <p>16 record.)</p> <p>17 BY MS. LOCKARD:</p> <p>18 Q. So you don't -- bless you.</p> <p>19 You don't intend to offer any opinions in</p> <p>20 this case criticizing the use of recycled solvents,</p> <p>21 do you?</p> <p>22 MR. STANOCH: Objection.</p> <p>23 THE WITNESS: No. As far as I can</p> <p>24 remember from my report, I don't speak at all to</p> <p>25 recycled solvents, although FDA speaks about that in</p>	<p style="text-align: right;">Page 304</p> <p>1 A. No. And my understanding is that a</p> <p>2 quality agreement is not pertinent to the purchase</p> <p>3 of a drug substance from a manufacturer by a</p> <p>4 drug-product manufacturer.</p> <p>5 Q. You were asked about Teva's submission of</p> <p>6 their CBE-30 --</p> <p>7 A. Yes.</p> <p>8 Q. -- for the change in ZHP supply of API; do</p> <p>9 you recall that?</p> <p>10 A. I do recall that.</p> <p>11 Q. Based on your experience, do you have any</p> <p>12 concerns with the use of the CBE-30 to convey those</p> <p>13 changes to FDA by Teva?</p> <p>14 MR. STANOCH: Objection.</p> <p>15 THE WITNESS: No, I think Teva, Watson at</p> <p>16 the time, was following FDA guidance, and if FDA had</p> <p>17 any concerns, they could certainly have communicated</p> <p>18 that to Teva right away. And they could have asked</p> <p>19 Teva to wait and they could have converted it to a</p> <p>20 postapproval supplement.</p> <p>21 BY MS. LOCKARD:</p> <p>22 Q. Did they do that?</p> <p>23 A. They did not. In fact, in both instances,</p> <p>24 they approved very rapidly the CBE-30, within days</p> <p>25 of its submission.</p>
<p style="text-align: right;">Page 303</p> <p>1 their guidance as a source of nitrosamine</p> <p>2 impurities.</p> <p>3 BY MS. LOCKARD:</p> <p>4 Q. Which guidance are you referring to?</p> <p>5 A. The 2021 nitrosamine impurities guidance.</p> <p>6 Q. You aren't aware of any FDA guidance in</p> <p>7 2018 or prior that identified recycled solvents as a</p> <p>8 source of impurities, are you?</p> <p>9 A. No. And to me --</p> <p>10 MR. STANOCH: Objection.</p> <p>11 THE WITNESS: Oh, I'm sorry.</p> <p>12 To me it's an example of how FDA and</p> <p>13 industry learned a great deal from this experience</p> <p>14 beginning in 2018.</p> <p>15 BY MS. LOCKARD:</p> <p>16 Q. Ultimately, is it important to your review</p> <p>17 and opinions whether Mylan was using recycled</p> <p>18 solvents or not in the API it supplied Teva?</p> <p>19 MR. STANOCH: Objection.</p> <p>20 THE WITNESS: No, to me it doesn't impact</p> <p>21 my report one way or the other.</p> <p>22 BY MS. LOCKARD:</p> <p>23 Q. Does the presence or absence of a quality</p> <p>24 agreement with Mylan and Teva impact your opinions</p> <p>25 in your report in any way?</p>	<p style="text-align: right;">Page 305</p> <p>1 Q. You were shown a press release about</p> <p>2 Ranbaxy and a negotiated guilty plea they entered</p> <p>3 with respect to their products; do you remember</p> <p>4 that?</p> <p>5 A. I do see it. As a matter of fact, it's</p> <p>6 still on my screen. I'm looking at it to my right.</p> <p>7 Q. And you have read through this document,</p> <p>8 or to some extent; is that correct?</p> <p>9 A. I have an understanding of what it's</p> <p>10 saying.</p> <p>11 Q. And to the extent that the document itself</p> <p>12 and the negotiated plea deal suggests that there was</p> <p>13 some retrospective determination that Ranbaxy</p> <p>14 products were determined to be adulterated, is that</p> <p>15 analogous in any way to the situation with Teva's</p> <p>16 products?</p> <p>17 MR. STANOCH: Objection to form.</p> <p>18 THE WITNESS: This entire matter with</p> <p>19 Ranbaxy, to me, it is a completely different set of</p> <p>20 circumstances.</p> <p>21 First of all, it involves the Department</p> <p>22 of Justice. It has a huge civil penalty. It</p> <p>23 involves fraud and false statements to the agency.</p> <p>24 It certainly involves GMP violations.</p> <p>25 And what happens when you see an</p>

<p style="text-align: right;">Page 306</p> <p>1 announcement like this, you are seeing the result of 2 years of effort on the part of FDA and the 3 Department of Justice to have Ranbaxy agree to a set 4 of statements, including the statement about 5 adulteration in the prior years. 6 So I would say it has no relationship at 7 all to my current report or my opinions. 8 BY MS. LOCKARD: 9 Q. So in the Ranbaxy situation, was the 10 language that was referenced about adulteration, to 11 your knowledge, was that the product of negotiation 12 between Ranbaxy -- 13 MR. STANOCH: Objection to the -- 14 (Reporter clarification.) 15 BY MS. LOCKARD: 16 Q. Government? 17 THE REPORTER: Thank you. 18 MR. STANOCH: Objection. Objection. 19 THE WITNESS: Well, to the extent I know 20 what happened here, and I know it was a very 21 detailed effort on the part of the agency, yes, it 22 was a negotiated settlement where Ranbaxy and FDA 23 and the Department of Justice are agreeing to the 24 statement that appears on my screen. 25</p>	<p style="text-align: right;">Page 308</p> <p>1 BY MS. LOCKARD: 2 Q. The confidentiality of DMFs was discussed 3 earlier today. Do you remember that? 4 A. I do. 5 Q. Is there any part of the DMF that FDA 6 actually considers to be open? 7 A. If we look at some of the documents I 8 cited, you will see that FDA considers the DMF 9 entirely confidential. In Europe sometimes they 10 talk about an open part or a closed part, but FDA 11 thinks of it as all closed, all confidential. 12 Q. You had said that theoretically you 13 suppose companies could decide on their own to 14 share, but are you familiar with that happening in 15 this case? 16 MR. STANOCH: Objection. 17 THE WITNESS: I'm not, and it seems 18 unusual. It seems to undercut the purpose of the 19 DMF, which is to keep some parts of it confidential. 20 What the buyer, in this case the ANDA 21 holder, would see is the certificate of analysis, 22 which is the specification you use to test the drug 23 substance, and that's all they would see. 24 BY MS. LOCKARD: 25 Q. And in this situation, would you expect</p>
<p style="text-align: right;">Page 307</p> <p>1 BY MS. LOCKARD: 2 Q. To your knowledge, has Teva been involved 3 in any DOJ investigation, criminal proceeding, FDA 4 fines, like that described in the Ranbaxy press 5 release with respect to its -- 6 A. No, I have not -- 7 (Whereupon, a brief discussion off the 8 record.) 9 BY MS. LOCKARD: 10 Q. Okay. My question to you, Dr. Williams, 11 was: To your knowledge, has Teva been involved in 12 any DOJ investigation, criminal proceeding, FDA 13 fines or fraud with respect to its valsartan like 14 that that was described in this Ranbaxy press 15 release that you were provided today? 16 MR. STANOCH: Objection. 17 THE WITNESS: Not at all. 18 BY MS. LOCKARD: 19 Q. Does this Ranbaxy press release and the 20 findings in any way undercut your opinions that you 21 have rendered in this case about Teva's valsartan 22 not being adulterated? 23 MR. STANOCH: Objection. 24 THE WITNESS: No, not at all. 25</p>	<p style="text-align: right;">Page 309</p> <p>1 Teva and its API suppliers to share the DMF or 2 supply Teva with anything other than the certificate 3 of analyses? 4 MR. STANOCH: Objection to form. 5 THE WITNESS: I didn't see any documents 6 otherwise, so my belief is that the two 7 drug-substance manufacturers were keeping their DMF 8 confidential, as is typical of the way DMFs are 9 handled. 10 BY MS. LOCKARD: 11 Q. Right. So is it surprising to you if you 12 learn that the companies in this case didn't -- did 13 not share the DMF portion? 14 A. That would not be surprising. 15 MR. STANOCH: Objection. 16 THE WITNESS: That would not be 17 surprising. That would be typical. 18 BY MS. LOCKARD: 19 Q. Now, you were asked a line of questions 20 referencing back to your report, and it was under 21 "The FDA Drug Approval Process" section in your 22 report. You were asked about a line that said, "A 23 recall is a voluntary action taken by a company to 24 remove a defective drug product from the market." 25 Do you recall that?</p>

<p style="text-align: right;">Page 310</p> <p>1 MR. STANOCH: Objection.</p> <p>2 THE WITNESS: I do recall that.</p> <p>3 BY MS. LOCKARD:</p> <p>4 Q. And had you taken that as a quote from an</p> <p>5 FDA general statement about drug recalls?</p> <p>6 MR. STANOCH: Objection.</p> <p>7 THE WITNESS: I think if we look at the</p> <p>8 FDA website and see what it says about recalls, that</p> <p>9 is what it says. That's the terminology they use.</p> <p>10 BY MS. LOCKARD:</p> <p>11 Q. Can a recall occur for reasons other than</p> <p>12 a defective product?</p> <p>13 MR. STANOCH: Objection.</p> <p>14 THE WITNESS: Well, I would say this is an</p> <p>15 interesting example, because at the time Teva and</p> <p>16 FDA agreed to recall their valsartan products, there</p> <p>17 was no understanding the products were defective.</p> <p>18 They were not defective. FDA had not set limits on</p> <p>19 nitrosamine impurities. But still FDA and Teva</p> <p>20 agreed that they should come off the market because</p> <p>21 of the presence of the nitrosamine impurities.</p> <p>22 Later on, when FDA set limits, you could</p> <p>23 say, well, they might have been considered</p> <p>24 adulterated, but in the summer of 2018, with regard</p> <p>25 to the ZHP drug substance, I do not see them as</p>	<p style="text-align: right;">Page 312</p> <p>1 Q. Let's see, actually.</p> <p>2 A. Oh.</p> <p>3 Q. Pull that out of my --</p> <p>4 A. Oh.</p> <p>5 Q. It's there.</p> <p>6 A. Yes. I see it, thank you.</p> <p>7 Q. Are you familiar with the Pharmacy Times?</p> <p>8 A. Yes, somewhat.</p> <p>9 Q. Have you ever seen this article before</p> <p>10 today?</p> <p>11 A. No, I have not.</p> <p>12 Q. Do you see what the date on this article</p> <p>13 was?</p> <p>14 A. June 29th, 2021.</p> <p>15 Q. Are you familiar with Edwin Gump?</p> <p>16 A. I actually am not.</p> <p>17 Q. Are you familiar with the Small Molecules</p> <p>18 Department at U.S. Pharmacopeia, USP?</p> <p>19 A. Yes.</p> <p>20 MR. STANOCH: Objection. Form.</p> <p>21 THE WITNESS: I would say I helped create</p> <p>22 that department when I first came to USP in 2000.</p> <p>23 BY MS. LOCKARD:</p> <p>24 Q. There is also a reference on the second</p> <p>25 page to the USP Nitrosamines Joint Subcommittee.</p>
<p style="text-align: right;">Page 311</p> <p>1 being defective products.</p> <p>2 BY MS. LOCKARD:</p> <p>3 Q. So just to be clear, do you hold any</p> <p>4 opinion that the valsartan products that were sold</p> <p>5 to customers by Teva were sold in a defective state?</p> <p>6 MR. STANOCH: Objection to form.</p> <p>7 THE WITNESS: I wouldn't use those words,</p> <p>8 and that is not part of my opinion.</p> <p>9 BY MS. LOCKARD:</p> <p>10 Q. Does the presence -- does the sheer</p> <p>11 presence of any nitrosamine render a product</p> <p>12 defective?</p> <p>13 MR. STANOCH: Objection to form.</p> <p>14 THE WITNESS: No. I would say,</p> <p>15 particularly if we look at the nitrosamine guidance,</p> <p>16 FDA will allow nitrosamine impurities in ingredients</p> <p>17 and products as long as they stay within acceptable</p> <p>18 intake limits.</p> <p>19 BY MS. LOCKARD:</p> <p>20 Q. So is it your opinion that if a drug</p> <p>21 product is sold -- well, strike that.</p> <p>22 You were asked about Exhibit 14. See if</p> <p>23 we can get a copy of that for you. It was an</p> <p>24 interview in the Pharmacy Times.</p> <p>25 A. I don't think I have that.</p>	<p style="text-align: right;">Page 313</p> <p>1 Was that a subcommittee in effect at FDA when you</p> <p>2 were there?</p> <p>3 A. No, it was not.</p> <p>4 Q. When was that formed, if you know?</p> <p>5 A. I actually don't know, and I'm not sure I</p> <p>6 see where you are reading. Could you help me,</p> <p>7 Ms. Lockard?</p> <p>8 Q. If you are looking at the bottom of what</p> <p>9 is page 2. Are you with me there?</p> <p>10 A. Actually, I am still not. There is</p> <p>11 something where it speaks to a subcommittee of an</p> <p>12 expert committee?</p> <p>13 Q. Yeah, it is the very end of page 2, where</p> <p>14 it says "Alana Hippensteele," she says, "That's</p> <p>15 fascinating."</p> <p>16 A. Oh.</p> <p>17 Q. "What is the USP Nitrosamines Joint</p> <p>18 Subcommittee" --</p> <p>19 A. Yes, I see.</p> <p>20 Q. -- "and why was it established?" Do you</p> <p>21 see that?</p> <p>22 A. Yes, I can, you know, understand, I think,</p> <p>23 what that subcommittee was doing and how it was</p> <p>24 formed.</p> <p>25 Q. Okay. Can you explain briefly your</p>

<p style="text-align: right;">Page 314</p> <p>1 understanding of what it was doing and how it was 2 formed? 3 A. Well, USP has the Council of Experts, 4 which has many expert committees. But the expert 5 committees have the possibility of forming 6 subcommittees, drawing on expertise from different 7 committees. So I see a subcommittee being formed 8 jointly from several expert committees to consider 9 particularly the topic of nitrosamines in 10 small-molecule medicines. 11 Q. To your knowledge, did the USP 12 Nitrosamines Joint Subcommittee exist before 2018? 13 A. I don't know that. As far as I know, it 14 didn't exist. 15 Q. All right. So if you turn to page 4, I 16 believe you were asked to read some of the text on 17 this page, and you were asked if you agreed with it. 18 Do you remember that? 19 A. Page 4. Is this the one down at the 20 bottom where he's talking about the grilled burger? 21 Q. Let me see. I know the pages aren't 22 numbered, which makes it difficult, but I'm just 23 counting three, four. 24 A. Oh, okay. All right. Thank you. 25 Q. Okay. So the very last paragraph on</p>	<p style="text-align: right;">Page 316</p> <p>1 Q. And if you skip down, midway on the page 2 Edwin Gump is speaking. 3 A. He is. 4 Q. He says, "It's a good question. So, one 5 of the things that I think the pharmaceutical 6 industry has generally for the most part done very 7 well is look at impurities." Do you agree with 8 that? 9 A. I do. 10 Q. He goes on to say, "I think nitrosamines, 11 for the reasons I just described, are kind of a 12 unique case where they can sort of crop up." Do you 13 agree with that? 14 A. I do agree with that. 15 Q. He goes on, "They aren't necessarily 16 readily identified as part of the components during 17 the manufacturing process, and so they sort of slip 18 through." Is that your understanding as well? 19 A. I think I could agree with that. 20 Q. "Whereas, other types of impurities, I 21 think, manufacturers have a" "better handle on how 22 to control those." 23 A. Yes, I think he is speaking to what I was 24 trying to comment on as well, that there are sort of 25 general ways of dealing with impurities, but the</p>
<p style="text-align: right;">Page 315</p> <p>1 page 4, that begins, "So, and again"; do you see 2 that? 3 A. Yes, I do see that. 4 Q. Oh, good. Can you read that paragraph as 5 well? 6 A. "So, and again, I think I mentioned, we're 7 talking about really ultratrace levels, parts per 8 million, part per billion. So, these are not easy 9 analyses to perform. They require highly complex 10 analytical equipment, and with any test, you need to 11 kind of have what's the control to that test." 12 Q. So do you agree with that statement? 13 A. I certainly do. 14 Q. And if you look at the following page, 15 first paragraph. 16 A. Yes, and I can read it, but I think what 17 USP is doing is talking about its reference 18 materials, and they are talking about reference 19 materials for nitrosamine impurities. 20 Q. And in Paragraph 2 it says, "So, having 21 the reference standards is a really important tool 22 for manufacturers." 23 A. Yeah. 24 Q. Did I read that correctly? 25 A. Yes, that's quite true.</p>	<p style="text-align: right;">Page 317</p> <p>1 nitrosamine impurities are -- as FDA said, are very 2 unusual, unexpected. You have to think that they 3 may be there, and then even when you think that, 4 they are at very low levels and require very special 5 techniques to measure. 6 Q. So towards the bottom of the page, 7 finally, Mr. Gump is saying, "It really is, I think, 8 a lot better than people think. You tend to hear 9 about the few problems that occur, but you don't 10 hear about the millions or billions of pills that 11 get distributed every year and help people deal with 12 their health conditions." Do you agree with that 13 sentiment? 14 A. I can certainly attest to that. 15 Q. So, Dr. Williams, you know, just to be 16 clear for the record, you weren't really asked much 17 about your report and your opinions in it. But have 18 you heard anything today that causes you to change 19 your opinions as stated in your expert report? 20 MR. STANOCH: Objection to form. 21 THE WITNESS: No, nothing at all. 22 BY MS. LOCKARD: 23 Q. Have you been shown any documents today or 24 testimony that changes your opinion in any way? 25 A. No.</p>

<p>Page 318</p> <p>1 Q. So in terms of, really, if we can get to 2 the heart of your opinions, what are your core 3 opinions in this case? 4 MR. STANOCH: Objection. 5 THE WITNESS: You know, the way I would 6 summarize those, I think they appear in the last 7 page or two of my report, and I'll try to say it 8 this way. 9 Teva's products, all four 10 valsartan-containing drug products were always 11 pharmaceutically equivalent and bioequivalent to the 12 Diovan reference listed drugs made by Novartis. 13 While they were in the market, they were always 14 AB-rated by FDA. They were not misbranded because 15 FDA required them to have substantively the same 16 label as Diovan. 17 And they were not adulterated in my view 18 until -- and you could even debate it after that 19 point, but they certainly were not adulterated or 20 defective until FDA issued warning letters to ZHP 21 and Mylan or when FDA set limits in December of 22 2019. 23 So what you have -- and I said it in the 24 report, it's a very unusual situation, where we all 25 know nitrosamine impurities can be genotoxic. We</p>	<p>Page 320</p> <p>1 that Teva did anything wrong and everything right. 2 MS. LOCKARD: I don't have any more 3 questions for you at this time. I imagine there may 4 be more questions. Thank you, Dr. Williams. And I 5 may follow up. 6 EXAMINATION 7 BY MR. STANOCH: 8 Q. Dr. Williams, prior to your 9 question-and-answer session with Ms. Lockard, you 10 spoke with her during the lengthy 35-minute break, 11 didn't you? 12 MS. LOCKARD: Object to form. 13 Argumentative. 14 THE WITNESS: I would say I sat there and 15 listened to her talk out how she was going to 16 question me, but I really didn't engage in that 17 discussion in any substantive way. 18 MR. STANOCH: Stand by. 19 Nothing further, Doctor. 20 MS. LOCKARD: Any other questions from 21 others? 22 MR. STANOCH: And, Counsel, I'll just ask 23 on the record that the binder of potential exhibits 24 be destroyed or returned to me without looking at 25 it, please.</p>
<p>Page 319</p> <p>1 know they are very low level. They are hard to 2 measure. They can creep into a product, as Dr. Gump 3 said. 4 And FDA and Teva in the summer of '22 5 (verbatim) were faced with this issue. Well, we 6 have got them there. What are we going to do? And 7 FDA and Teva working together decided to recall, 8 first, all the ZHP products from the market before 9 there was any possibility of a decision about 10 adulteration, and then subsequently, after the 11 Swissmedic report, all the Mylan product from the 12 market, again, before there was any possibility of a 13 decision about adulteration. 14 As I said in the report, this is not a 15 failure. This is a success story where a 16 responsible company is making a huge effort to 17 protect consumers, to protect patients, and FDA is 18 working very hard to find out what is going on. 19 It spills over into other products. It 20 keeps spilling over into other products. And now 21 FDA is asking that essentially all chemical 22 medicines in the market or being developed for the 23 market be assessed for nitrosamine impurities. 24 I'm gratified with the effort. This is 25 how drug regulation advances. And I just don't see</p>	<p>Page 321</p> <p>1 MS. LOCKARD: All right. I did take the 2 exhibits you used out of the binder. 3 MR. STANOCH: That's fair. I understand. 4 Thank you. 5 MS. LOCKARD: I'll put them back. But I 6 didn't remove the ones that you haven't used and I 7 haven't looked at all of those, so -- 8 MR. STANOCH: I appreciate that. Thank 9 you, Counsel. 10 THE VIDEOGRAPHER: Anything further on the 11 record? 12 Okay. Well, this concludes today's 13 deposition of Dr. Roger Williams. We are going off 14 the record at 4:24. 15 (Whereupon, the deposition was concluded 16 at 4:24 p.m.) 17 18 19 20 21 22 23 24 25</p>

<p style="text-align: right;">Page 322</p> <p style="text-align: center;">INSTRUCTIONS TO WITNESS</p> <p>Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.</p> <p>After doing so, please sign the errata sheet and date it.</p> <p>You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.</p> <p>It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.</p>	<p style="text-align: right;">Page 324</p> <p style="text-align: center;">ACKNOWLEDGMENT OF DEPONENT</p> <p>I, _____, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.</p> <p>_____ ROGER WILLIAMS, M.D. DATE</p>
<p style="text-align: right;">Page 323</p> <p style="text-align: center;">ERRATA SHEET</p> <p>PAGE LINE CHANGE</p> <p>_____ REASON: _____</p> <p>PAGE LINE CHANGE</p> <p>_____ REASON: _____</p> <p>PAGE LINE CHANGE</p> <p>_____ REASON: _____</p> <p>PAGE LINE CHANGE</p> <p>_____ REASON: _____</p> <p>PAGE LINE CHANGE</p> <p>_____ REASON: _____</p>	<p style="text-align: right;">Page 325</p> <p>STATE OF CALIFORNIA) COUNTY OF YOLO)</p> <p>I, ELAINA BULDA-JONES, a Certified Shorthand Reporter of the State of California, duly authorized to administer oaths pursuant to Section 2025 of the California Code of Civil Procedure, do hereby certify that</p> <p>ROGER WILLIAMS, M.D.,</p> <p>the witness in the foregoing deposition, was by me duly sworn to testify the truth, the whole truth and nothing but the truth in the within-entitled cause; that said testimony of said witness was reported by me, a disinterested person, and was thereafter transcribed under my direction into typewriting and is a true and correct transcription of said proceedings.</p> <p>I further certify that I am not of counsel or attorney for either or any of the parties in the foregoing deposition and caption named, nor in any way interested in the outcome of the cause named in said deposition dated the 22nd day of February, 2022.</p> <p>ELAINA BULDA-JONES, CSR 11720</p>

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